

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

_____	x	
	:	
THE CITY OF HUNTINGTON,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01362
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

_____	x	
	:	
CABELL COUNTY COMMISSION,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01665
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

BENCH TRIAL - VOLUME 34
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JULY 2, 2021

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1 PROCEEDINGS had before The Honorable David A.
2 Faber, Senior Status Judge, United States District
3 Court, Southern District of West Virginia, in
4 Charleston, West Virginia, on July 2, 2021, at 9:00
5 a.m., as follows:

6 THE COURT: All right.

7 Do you want to call your witness?

8 MR. SCHMIDT: Yes, Your Honor. We're ready to go,
9 if that works for the Court.

10 THE COURT: Yes, please.

11 COURTROOM DEPUTY CLERK: Sir, would you please
12 state your name?

13 THE WITNESS: Christopher Gilligan.

14 COURTROOM DEPUTY CLERK: Thank you. Please raise
15 your right hand.

16 **DR. CHRISTOPHER GILLIGAN, DEFENSE WITNESS, SWORN**

17 COURTROOM DEPUTY CLERK: Thank you. Please take a
18 seat.

19 THE COURT: Good morning, sir.

20 THE WITNESS: Good morning.

21 MR. SCHMIDT: Your Honor, it's good to be back.
22 We call Chris Gilligan as our first witness.

23 May we proceed?

24 THE COURT: Well, it's good to see you, sir.

25 MR. SCHMIDT: Thank you.

1 THE COURT: We missed you.

2 MR. SCHMIDT: I missed being here. I missed you.

3 May we proceed?

4 THE COURT: Yes, please.

5 MR. SCHMIDT: Okay.

6 **DIRECT EXAMINATION**

7 **BY MR. SCHMIDT:**

8 **Q.** Good morning, Dr. Gilligan. Please introduce yourself
9 to the Court, if you would, in terms of name and your
10 position, please.

11 **A.** Good morning. I'm Chris Gilligan and I serve as the
12 Chief of the Division of Pain Medicine at Brigham and
13 Women's Hospital in Boston.

14 **Q.** What is it that has made you dedicate your career to
15 pain medicine, the discipline that you just mentioned?

16 **A.** When you think about what brings a patient to a doctor,
17 one of the main reasons, one of the primary reasons the
18 patients come, is to get relief of -- from pain and, also,
19 for patients who have severe chronic pain conditions, those
20 conditions, not just because of the obvious suffering from
21 pain, but they also prevent patients from -- from
22 functioning, from working; in many cases, taking care of
23 their families, doing the things they need to do and want to
24 do and essentially can take their life away. And so, when
25 we're able to successfully treat those patients, it's

1 incredibly rewarding.

2 **Q.** Prescription opioids over the course of your career,
3 have they been an important part of pain treatment and pain
4 management?

5 **A.** Yes, they have.

6 **Q.** Who's charged with making the judgment about when and
7 by whom prescription opioids should be used?

8 **A.** Principally, that's doctors. It's clinicians who are
9 in the exam room with the patient and are getting the
10 information about the patient's case, are examining the
11 patient, have the training and the education to make that
12 decision and, therefore -- and also have the responsibility
13 and the authority to make that decision.

14 **Q.** From your experience, do distributors play a role in
15 deciding whether doctors prescribe opioids or other
16 medicines?

17 **A.** No, they do not.

18 **Q.** Do they play a role in determining the level of opioids
19 that doctors prescribe?

20 **A.** No.

21 **Q.** And I'd like to dive into those opinions over the
22 course of our exam but, first, I want to take a step back
23 and spend a little more time giving the Court a sense of
24 your background, if we could. Let me start off by asking
25 where you went to college?

1 **A.** I went to Harvard College.

2 **Q.** And what did you do after college and before medical
3 school?

4 **A.** I went to Cambridge University in England and did an M.
5 Phil, an M. Phil degree, a Masters degree.

6 **Q.** Where did you go to medical school after that?

7 **A.** I went to Yale Medical School.

8 **Q.** What was it that made you decide you wanted to go to
9 medical school?

10 **A.** When I was 15, I spent a summer in France and stayed
11 with a family where the father was a doctor and got to know
12 him very well and had tremendous respect for him, and
13 decided that I wanted to be a -- wanted to follow that path.

14 **Q.** Okay. And you've done some different things over the
15 course of your career that I want to briefly touch on.
16 Could you first walk us through what you did between
17 graduating from medical school up to the year 2000?

18 **A.** Yes. So, I graduated from medical school in 1996. I
19 did a one-year surgical internship at New York Hospital in
20 New York.

21 After that, I moved up to Boston to Brigham and Women's
22 Hospital to serve as a surgery resident.

23 Then, I got to the two-year research portion of a
24 seven-year surgery residency and I got permission to go back
25 to school during that two-year research period. So, I went

1 to Harvard Business School.

2 After Harvard Business School, I was intending to just
3 go back to my surgery residency, but my professors at the
4 business school said you need to get some -- some business
5 experience. I'd only been a doctor. So, I did Life Science
6 Venture Capital and then I also went and I served in the
7 Army in Israel. I'm -- my family -- my mother is Jewish,
8 I'm Jewish, and I went to Israel, did my military service
9 there.

10 **Q.** And how long did you serve in the military in Israel?

11 **A.** About a year and a half.

12 **Q.** Did that include a combat function?

13 **A.** Yes, it did.

14 **Q.** And can you tell us just a little bit about that?

15 **A.** I was a battalion doctor in the Golani Brigade, which
16 is an infantry brigade. So, we were principally tasked with
17 dealing with a lot of different things.

18 **Q.** Okay. Did you do further medical training after
19 completing that service and that work you described in 2004?

20 **A.** Yes. After that, I went back to Brigham and Women's
21 and did the combined emergency medicine residency at Brigham
22 and Women's and Mass General Hospital. I shifted from
23 surgery to emergency medicine and completed my emergency
24 medicine residency there and then I stayed on at Mass
25 General to do a pain medicine fellowship.

1 **Q.** And what prompted the shift from a surgery focus to a
2 pain medicine focus for you?

3 **A.** So, I had been on a cardiac surgery track and I saw
4 that cardiac surgery was really -- patients were being
5 better treated by minimally invasive therapies and
6 interventional cardiologists and such were developing. And
7 I realized that in pain medicine there was an element where
8 we could do the same thing for patients to try to -- to try
9 to develop better, simpler, safer procedures and treatments
10 to help patients get better.

11 **Q.** As I understand your CV, since finishing that
12 fellowship in anesthesia and pain medicine, you've been at
13 different teaching hospitals in Boston; is that correct?

14 **A.** That is right. After finishing the fellowship, I
15 stayed on staff at Mass General Hospital, which is one of
16 the teaching hospitals for Harvard Medical School.

17 Then I went to Beth Israel Deaconess Medical Center,
18 which is another of the teaching hospitals for Harvard
19 Medical School.

20 And then, since 2016, I've been serving as the Chief at
21 Brigham and Women's, which is also one of Harvard's teaching
22 hospitals.

23 **Q.** And can you comment just on the standing of Brigham and
24 Women's in the -- in the medical -- in the broader medical
25 community?

1 **A.** It's one of the big academic medical centers in Boston
2 charged with taking care of patients, doing research to try
3 to advance our different fields, and teaching medical
4 students, residents, fellows. Hopefully, the next
5 generation of leaders.

6 **Q.** In terms of teaching, is it affiliated with any
7 universities?

8 **A.** So, it is a teaching hospital for Harvard Medical
9 School.

10 **Q.** Are you -- are you board certified in any areas?

11 **A.** I'm board certified in emergency medicine and in pain
12 medicine.

13 **Q.** Beyond being board certified yourself, do you play any
14 role in the board certification process for other doctors?

15 **A.** I do. I write the -- some of the board examination
16 questions for the Pain Medicine Boards.

17 **Q.** Having walked through your background --

18 MR. SCHMIDT: May I approach the witness, Your
19 Honor?

20 THE COURT: Yes, please.

21 BY MR. SCHMIDT:

22 **Q.** I'd like to just dive into a little bit of -- a little
23 bit more detail into some of the areas of your background.

24 MR. SCHMIDT: Am I going to break anyone's heart
25 if I erase this?

1 THE COURT: You're a day late on the birthday
2 cake.

3 MR. SCHMIDT: That's really sweet.

4 BY MR. SCHMIDT:

5 Q. Throughout your career, have you been involved in
6 patient care, teaching and research?

7 A. Yes. That would be a good description of -- we talk
8 about a three-part mission, which is our mission, and that's
9 a good description of how I've spent my time.

10 Q. Okay. I'm going to just walk through some of those,
11 starting with patient care. Can you give us a sense of the
12 range of pain conditions that, in your work, you treat?

13 A. So, we treat really a broad and I think a complete
14 range. We treat patients with back and neck pain, hip and
15 knee pain from arthritis. We treat a lot of patients.
16 We're the hospital associated with the Dana-Farber Cancer
17 Institute. We treat conditions that are just defined by the
18 pain, things like shingles. We treat a lot of patients with
19 headaches.

20 And then, a wide range. Patients, for example, may
21 have an autoimmune condition like rheumatoid arthritis,
22 things like that, that cause pain, and we treat -- we treat
23 that, as well.

24 Q. Is that true or not true in terms of the patient
25 population that you see? Is it a narrow range, a focused

1 range, or a broad range?

2 **A.** So, we're a teaching hospital and we see the entire
3 range. We see -- we see patients who are homeless. We see
4 patients who are royalty and fly in from other countries.

5 **Q.** Do you have just -- not to the person, but a rough
6 estimate of what order of magnitude of patients you've seen
7 and cared for over the course of your career?

8 **A.** So, I see patients two and a half days a week. A
9 typical clinic day for me is about 25 patients give or take.
10 My whole career in pain medicine, I've seen -- at least that
11 many days a week I've spent time seeing patients. Other
12 times, it's been more than that. So -- and I finished
13 fellowship in 2008.

14 **Q.** So, are we talking hundreds more, thousands?

15 **A.** I think -- I think it's thousands.

16 **Q.** Okay. And could you orient us to how that tracks in
17 the real world just to illustrate when was the last time you
18 saw a patient?

19 **A.** Yesterday afternoon right before I went to the airport.

20 **Q.** Okay. When is the next time you will see a patient?

21 **A.** I'm taking vacation next week.

22 **Q.** Okay.

23 **A.** So, the following Monday morning.

24 **Q.** Got it.

25 Do you -- in addition to seeing patients yourself, do

1 you also supervise other physicians who are responsible for
2 providing pain management medical care to patients?

3 **A.** Yes. So, we have a pain medicine fellowship and every
4 year we train ten fellows in pain medicine. In addition, we
5 have the residents from Brigham and we also have a lot of
6 residents who come through and medical students who come
7 through.

8 **Q.** Could you give us a sense of what that entails when it
9 comes to the people you're overseeing, their medical
10 treatment and, specifically, their use of prescription
11 medicines?

12 **A.** So, we see patients typically together with the
13 trainees, the fellows, or the residents, to evaluate the
14 patient together, make a plan together, and then they --
15 they also participate with us in writing prescriptions,
16 doing procedures, et cetera.

17 **Q.** Are there any other leadership roles that you play at
18 Brigham and Women's?

19 **A.** Yes. So, I'm -- I'm one of the Vice Chairs of
20 Anesthesia. I'm also the Director of the Spine Center at
21 Brigham and Women's Hospital. And then I serve on the
22 Executive Committee of the Brigham Comprehensive Opioid
23 Response and Education Committee, which is a committee at
24 the Brigham responsible for, as the name implies, both
25 overseeing opioid prescribing and educating physicians and

1 other clinicians about opioid prescribing.

2 **Q.** Is that a steering committee?

3 **A.** That's a steering committee, yes.

4 **Q.** Okay. And could -- does serving on that steering
5 committee include any role in creating guidelines for
6 doctors?

7 **A.** Yes. We write the guidelines for clinicians at Brigham
8 and Women's about appropriate prescribing of opioids and
9 other -- and other related topics.

10 **Q.** Just at a high level, what is the purpose of guidelines
11 like that?

12 **A.** I would say the purpose is to try to give clinicians
13 guidance on essentially how to get it right. What is the
14 right balance? Everything in medicine is a balance of risk
15 and benefit and on a specific topic like that you're trying
16 to give guidance about how to best and most appropriately
17 get that decision right. Those are decisions that,
18 typically, the correct answer is not going to always be yes.
19 The correct answer won't always be no. And you're trying to
20 give people guidance about where the balance should lie.

21 **Q.** Let me shift gears and ask you about your teaching
22 work. Are you affiliated or are you on the faculty at any
23 medical school?

24 **A.** I'm on the faculty at Harvard Medical School.

25 **Q.** What do you teach there?

1 **A.** Really, the folks who I've mentioned, the fellows,
2 residents, medical students, where we teach them about the
3 field of pain medicine, how to practice it, how to evaluate
4 patients and the research, et cetera.

5 **Q.** And how long have you been doing that?

6 **A.** Since 2008.

7 **Q.** Over a decade? Lastly, your research, do you conduct
8 pain research?

9 **A.** Yes, I do. Principally clinical trials.

10 **Q.** And can you give us a sense of what that pain research
11 involves?

12 **A.** So, it's really a question of trying to take potential
13 new and perhaps better therapies and evaluate. Do they
14 work? Are they safe? Who do they work for? Who do they
15 not work for? What could be their role? Could they
16 represent a better way to treat at least a certain group of
17 patients that -- that we try to treat?

18 **Q.** Does that include doing research of clinical trials?

19 **A.** Very much so. Clinical trials is the focus of it.

20 **Q.** Are some of the treatments that you're looking at in
21 your clinical trial research potential alternatives to
22 prescription opioid treatments for pain?

23 **A.** Yes, they are because if we have other alternative
24 therapies that work well and are safe for certain patients
25 and can get them pain relief, return their function, et

1 cetera. Then, for at least a certain number of those
2 patients, you wouldn't need to be treating them with
3 opioids.

4 **Q.** Have you published studies and articles in peer-review
5 journals?

6 **A.** Yes, I have.

7 **Q.** And by my count you've got about a dozen; does that
8 seem right?

9 **A.** That might be about right.

10 **Q.** And I think I undersold you. I think it's about two
11 dozen, looking at my notes.

12 **A.** That seems more right.

13 **Q.** Okay. I've had trouble with my dozen counting in this
14 -- in this court. So, it pays to check my math, especially
15 for me.

16 Do you also serve as a peer reviewer for scientific
17 journals?

18 **A.** Yes, I do.

19 **Q.** Has that included leading medical journals?

20 **A.** Yes, it has.

21 **Q.** Can you give us a couple examples of that?

22 **A.** The Lancet, The New England Journal of Medicine, some
23 of the more well-regarded journals in the field,
24 specifically, of pain medicine.

25 **Q.** And that was going to be the next question I asked you.

1 Has that included specifically pain management journals in
2 addition to general journals like Lancet and like The New
3 England Journal of Medicine?

4 **A.** It has, yes.

5 **Q.** Have you also served in an editorial role in journals?

6 **A.** Yes. I serve on the Editorial Board of one of the pain
7 medicine journals and, in September, I'll become an Editor
8 in Chief of a different one.

9 **Q.** And last question in this area. Have you undertaken
10 service for the Department of Defense related to pain
11 treatments?

12 **A.** Yes. I evaluate grant applications with the Department
13 of Defense on topics in the field of pain medicine where
14 they're deciding which ones to fund, as they're trying to do
15 similar things to what we talked about, evaluate, find new
16 and better treatments for pain conditions.

17 **Q.** I'm going to put you on the spot a little bit, Dr.
18 Gilligan, and ask you a couple of questions on some of the
19 recognitions you've received, not wanting to make you feel
20 uncomfortable in doing so.

21 Over the course of your career have you received awards
22 for some of the work that you've done?

23 **A.** Yes, I have.

24 **Q.** And I want to just ask you basic questions about a few
25 of those. One was you have listed on your CV that you were

1 part of a summit on opioid abuse at the White House in 2014.

2 Can you give us a sense of what that involved?

3 **A.** So, it was -- as the name implies, it was a summit at
4 the White House looking at the topic of opioid abuse. I
5 think my role was to be there as a specialist in pain
6 medicine because to address that topic you both have to look
7 at the area of addiction medicine, but also, you have to
8 look at the topic of pain medicine because how are you going
9 to treat pain.

10 **Q.** You also have listed some citizenship awards and
11 something called a Fellowship Excellence Award. Can you
12 tell us what those are?

13 **A.** Those are recognitions from the hospitals, the
14 Department of Anesthesia, for -- I think for contributing to
15 the mission of the department and for -- for running a
16 fellowship in pain medicine that was well regarded.

17 **Q.** Okay. And this is the hardest one for me personally to
18 ask you about. It looks like you've gotten something from
19 the Boston Red Sox. Can you tell us about that?

20 **A.** They also give -- give an award, I think, for
21 physicians who they think have worked hard to treat their
22 patients and work in our community.

23 **Q.** Let me shift gears a little bit. Have you served as an
24 expert witness before this case?

25 **A.** Yes, I have.

1 Q. How much of your time does that kind of work make up?

2 A. That's typically a very small part of what I do.

3 Q. Have you served as an expert witness for the government
4 in prior matters?

5 A. Yes, I have.

6 Q. And without diving into details, can you give us just a
7 general sense of what that entails?

8 A. So, I served as an expert witness for the U. S.
9 Attorney's Office. I think that's Department of Justice and
10 the FBI for a doctor who was accused in a criminal case of
11 -- I think the accusation was stopping being a doctor and
12 being essentially a drug dealer.

13 Q. And I saw one time where you were asked to testify by
14 the government in a case involving an opioid company, but
15 you weren't allowed to do so. Can you tell us what happened
16 there?

17 A. Yeah. So, some executives at Insys Pharmaceuticals
18 were charged with criminal charges that were related to --
19 Insys produced opioids or does produce opioids. The defense
20 attorneys for them came, met with me a few times, asking me
21 to serve as a witness for the defense, an expert witness.

22 Then I went to my department. We have to get
23 permission from our department to serve as an expert
24 witness. The leadership in my department said that I should
25 not serve as an expert witness and I told them that.

1 Subsequently, the government --

2 **Q.** I'm sorry. Did you agree with that view?

3 **A.** Actually, I did, yes.

4 **Q.** Okay.

5 **A.** Subsequently, the attorneys from the government, from
6 the U. S. Attorney's Office, asked if I would serve as their
7 witness, their expert witness in that same case. I told
8 them that I was surprised because I told them about the
9 conversations I had had with Insys. They said they didn't
10 think it was problematic, but the judge said that I should
11 not serve as an expert witness since I had both talked to
12 the defense and then subsequently to the U. S. Attorney's
13 Office.

14 **Q.** Okay. You're being compensated for your work in this
15 case. Can you share with us your hourly rate?

16 **A.** My rate is \$800.00 per hour.

17 **Q.** And in terms of different prescription opioid cases
18 where we have worked with you on behalf of McKesson, how far
19 back in time does that reach?

20 **A.** For the different cases, I think it's about two years.

21 **Q.** Has your work included going back through the
22 literature developments in the medical field and reviewing
23 that kind of material?

24 **A.** Yes, it has.

25 **Q.** Has your work included making an effort to fully review

1 all of McKesson's documents, or ABDC's documents, or
2 Cardinal's documents?

3 **A.** No. I haven't done an in-depth review of all of their
4 documents, no.

5 **Q.** And why is that?

6 **A.** I'm a doctor. I'm an expert in pain medicine. I'm,
7 frankly, not an expert in healthcare distributors and their
8 business.

9 **Q.** Got it.

10 I want to just wrap up on some of these points.
11 Throughout the course of your career, has your work and your
12 training focused on the medical management of pain?

13 **A.** Yes, very much so.

14 **Q.** Have you been directly involved with the use of
15 prescription opioids and discussions about the standard of
16 care for using prescription opioids since you were in
17 medical school back in the 90s?

18 **A.** Yes, I have.

19 **Q.** And as part of your professional work and as a part of
20 your work in this case have you had occasion to study
21 prescribing patterns from before you were in medical school
22 in terms of what's reflected in literature and things like
23 that?

24 **A.** Yes, I have.

25 **Q.** From doing that work, have you reached opinions on pain

1 management and the use of prescription opioids in pain
2 management for purposes of this lawsuit?

3 **A.** Yes, I have.

4 **Q.** Are you offering all of the opinions you offer in those
5 areas to a reasonable degree of medical certainty?

6 **A.** I am.

7 MR. SCHMIDT: Your Honor, at this point, we move
8 to admit Dr. Chris Gilligan as expert in pain management and
9 the risks and benefits of prescription opioids.

10 THE COURT: Any objection? Hearing none, the
11 Court --

12 MR. FARRELL: Judge, yes. If you don't mind, may
13 I voir dire the witness?

14 THE COURT: Yes.

15 **CROSS EXAMINATION**

16 **BY MR. FARRELL:**

17 **Q.** Good morning, Dr. Gilligan.

18 **A.** Good morning.

19 **Q.** A couple of questions.

20 Are you licensed in West Virginia?

21 **A.** No, I am not.

22 **Q.** Have you ever practiced medicine in West Virginia?

23 **A.** No.

24 **Q.** Have you provided healthcare for West Virginians, to
25 your knowledge?

1 **A.** Not -- not that comes to mind immediately, no.

2 **Q.** And then, real quick, you mentioned the Chair of Pain
3 Medicine. In part of your administrative role or your
4 oversight of physicians, do you monitor the prescribing
5 practices of those doctors?

6 **A.** Yes, I do.

7 MR. FARRELL: No objection and no further
8 questions.

9 THE COURT: The Court finds that Dr. Gilligan is
10 an expert in the field of pain management and the risks and
11 benefits of prescription opioids.

12 Just curious, what was your Cambridge college?

13 THE WITNESS: Jesus.

14 THE COURT: Okay.

15 BY MR. SCHMIDT:

16 **Q.** So, Dr. Gilligan, I'd like to ask you about the
17 condition of pain and then ask you about prescription
18 opioids as a treatment for pain. Let's start with the pain
19 first. Could you tell us just at a high level from your
20 experience how pain impacts the patients you see and why
21 it's important to treat pain?

22 **A.** So, we see patients who their pain is at the level that
23 they're coming to go see a pain specialist. And many of our
24 patients have chronic pain conditions. And for a lot of
25 those patients it's -- their pain is severe, so just their

1 level of suffering is severe.

2 But also very, very important is that, in many cases,
3 they can't work or they can't work the way they want to. As
4 I mentioned before, they can't take care of their family the
5 way they want to. They can't participate in the community,
6 socialize, exercise, et cetera. And so, not only do they
7 have the suffering from the pain, but they have essentially
8 -- we talk about their life being taken away from them by
9 the pain and by the limitation in function from the pain.

10 So, frankly, some of these cases are -- if you're
11 sitting in the room with a patient are very, very brutal.

12 **Q.** Have you seen over the course of your career the impact
13 that pain directly has upon patients who suffer from it,
14 particularly chronic pain?

15 **A.** Yes. I would say on a daily basis when we're -- where
16 we're in clinic I see that.

17 **Q.** Are you familiar with published data on trying to
18 quantify the costs and the number of people affected by
19 pain, including chronic pain?

20 **A.** Yes, I am.

21 **Q.** I'd like to ask you about some of that data, if I may.
22 I'm going to show you a document that the Court has seen
23 before, but is not in evidence, MCWV-1170.

24 MR. SCHMIDT: May I approach, Your Honor?

25 THE COURT: Yes.

1 MR. SCHMIDT: And I apologize. I feel like I came
2 back and the big documents came back.

3 THE COURT: We cleaned out the documents while you
4 were gone, Mr. Schmidt.

5 MR. SCHMIDT: I know. I'm sorry.

6 BY MR. SCHMIDT:

7 Q. And so we know what we're looking at, Dr. Gilligan, if
8 we go to the second page of this document, it's titled --
9 and we can actually put it up on the screen.

10 MR. SCHMIDT: Can you switch that?

11 BY MR. SCHMIDT:

12 Q. It's entitled Relieving Pain in America. And then,
13 about halfway down, it says it's from the Institute of
14 Medicine. And if we go to the next page, the third page of
15 the document using the numbers in the lower left corner, we
16 can see near the bottom that it's from 2011. Are you
17 familiar with this document from the Institute of Medicine
18 and this report, Relieving Pain in America, from 2011?

19 A. Yes, I am.

20 Q. What is the Institute of Medicine?

21 A. So, the Institute of Medicine is a, frankly, very well
22 regarded group of physicians who have been recognized as
23 leaders and then they will be tasked by the government with
24 writing reports on certain topics that are important to the
25 health of Americans.

1 MR. SCHMIDT: On that basis, I'm going to move
2 this into evidence as a public report, but if there's an
3 objection, I can lay a little more foundation.

4 THE COURT: Is there any objection?

5 MR. FARRELL: No, Your Honor.

6 THE COURT: It's admitted.

7 MR. SCHMIDT: Okay. Thank you for that.

8 BY MR. SCHMIDT:

9 Q. Just in terms of this specific report, do you have an
10 understanding of how this report came to be?

11 A. Well, I think it was the government recognizing that
12 this is a topic that was very important to the health of
13 Americans and a need for data on the scope of the problem,
14 the state of treatments, et cetera, what were the unmet
15 needs in the areas that needed more research and they
16 brought together a group of experts in the field, as well as
17 patient representatives or others.

18 Q. All right. Let's look at Page 38 of this report, if we
19 could. And, again, I'm going to be using the numbers in the
20 bottom left corner, which differ from the numbers in the
21 actual document. And we have it up on the screen. I'm
22 going to read to you the last paragraph that carries over
23 onto Page 39 and ask you to comment on it.

24 It says pain is a universal experience but unique to
25 each individual. Is that something you see in your medical

1 practice?

2 **A.** Yes, it is.

3 **Q.** It then says across the lifespan, pain - acute and
4 chronic - and let me just pause right there. We're well
5 into this trial. I don't know if we've ever defined for the
6 Court what acute and chronic is from a pain management
7 doctor. Can you tell us what the difference between acute
8 and chronic pain is?

9 **A.** Sure. So, a couple of things. One is the time frame.
10 We typically talk about pain that's acute lasting 6 or 12
11 weeks; if pain is chronic, being longer than that, certainly
12 longer than 12 weeks.

13 There's also a distinction because acute pain is most
14 commonly associated something such as an injury. Someone
15 breaks their arm, there's actually a helpful signal in that.
16 If I -- if I break my arm and it hurts, it's telling me not
17 to move it, and there's some value in that.

18 Chronic pain is, almost by definition, more than
19 12 weeks and often is not, at that point, serving a useful
20 function. So, if I break my arm and twelve weeks later it's
21 been set, but it's still hurting severely, that's actually
22 not giving useful information, but there's suffering and
23 there's loss of function.

24 **Q.** So, to go back to the start of the sentence, it says
25 across the lifespan pain, acute and chronic, is one of the

1 most frequent reasons for physician visits, among the most
2 common reasons for taking medications, and a major cause of
3 work disability.

4 Have you seen all three of those things in your
5 practice in terms of pain as one of the most frequent
6 reasons people see doctors, one of the most frequent reasons
7 they take medicine, and one of the major causes of not being
8 able to work?

9 **A.** Yes. I have seen all three of those.

10 **Q.** All right. Let's jump ahead, if we could, to Page 47,
11 please. And there's a box there if we make it a little
12 larger that says pain by the numbers. And I want to just
13 walk through a couple pieces of data reported in this
14 report. The first piece of data reported says 100 million,
15 approximate number of U. S. adults with common chronic pain
16 conditions. Do you see that?

17 **A.** I do.

18 **Q.** Have you seen similar estimates of the number of
19 Americans who have chronic pain conditions?

20 **A.** Yes, I have.

21 **Q.** And I just want to differentiate between types of
22 chronic pain conditions. Is cancer pain a chronic pain
23 condition?

24 **A.** Cancer pain can also be a chronic pain condition. We
25 talk about chronic pain related to cancer and then chronic

1 non-cancer pain is one of the ways that we divide things.

2 **Q.** In terms of chronic cancer pain, can you characterize
3 that at all for the Court? Describe that pain.

4 **A.** So, chronic cancer pain, we do think of as a distinct
5 topic. In many instances, somebody may have advanced cancer
6 and they're going to have -- many of those patients will
7 have severe pain, but they also may have -- they,
8 unfortunately, have a limited life expectancy, frankly. For
9 those patients opioids are typically going to be really one
10 of the foundations of how we're going to treat the pain.
11 For most of those patients, opioids will play a central role
12 in how we're going to treat that pain.

13 **Q.** And you mentioned non-cancer chronic pain. Could you
14 tell us some of the conditions that cause non-cancer chronic
15 pain and characterize the relative severity of those?

16 **A.** So, for non-cancer chronic pain things like severe
17 low-back pain or neck pain, severe hip or knee pain
18 associated with arthritis and, actually, a whole host of
19 things. Some of the autoimmune conditions, rheumatoid
20 arthritis, Crohn's disease, et cetera. Chronic migraines.
21 And the list would go on.

22 **Q.** Okay. Just rounding out the questions that I was
23 asking you about this number, this is 2011, 100 million.
24 From your experience, has this number of adults in the U. S.
25 with common chronic pain conditions increased over time or

1 decreased over time?

2 **A.** I think that it's increased over time due to a few
3 things. One, the population has grown. It's gotten so much
4 older. Our population has gotten somewhat heavier and
5 weight is associated with knee and hip arthritis, et cetera.
6 So, I think that, overall, it has grown somewhat.

7 **Q.** Let's go to the next line and this is actually the
8 statistic we heard about with another expert, 560 to 635
9 billion conservative estimate of the annual cost of chronic
10 pain in America. Are you familiar-- have you seen
11 estimates like that in the literature in terms of trying to
12 estimate the economic consequences of chronic pain just on a
13 yearly basis?

14 **A.** Yes, I have.

15 **Q.** And are they consistent with this number which is north
16 of a half trillion?

17 **A.** Yes.

18 **Q.** If we then look at the -- let's skip the next bullet
19 which talks about state and federal government expenditures.
20 There's a number of percentages that run down here talking
21 about different pain conditions. Could you just walk
22 through the numbers there that you think are meaningful for
23 us to hear about?

24 **A.** Sure. So, I would look at the fourth bullet point for
25 women after having a baby and look for -- at that

1 percentage. 10 percent have persistent pain at one year. I
2 think that's significant.

3 I think, for the next bullet point, the patients who
4 have undergone surgery, specifically, the third dash there,
5 that 2 to 10 percent of these patients have chronic
6 postoperative pain that's severe. And what's important
7 there is that it's chronic. That's not right after surgery.
8 That's after they would have been expected to heal up, so to
9 speak.

10 I think the bullet point just below that, 5 percent of
11 the portion of American women 18 to 65 who have headache 15
12 or more days per month, I think that's quite significant.

13 And I think the second to last bullet point, the
14 percentage per U. S. nursing home residents, I would look at
15 the second dash there, that 17 percent have substantial
16 daily pain.

17 **Q.** A few more questions about this document.

18 MR. SCHMIDT: Could we go up to Page 162, please?

19 BY MR. SCHMIDT:

20 **Q.** And if we look here, there's a paragraph -- there's a
21 sub-header that says Patient Access to Opioids. Do you see
22 that?

23 **A.** I do.

24 **Q.** And it states in this 2011 Institute of Medicine
25 publication a reasonable degree of access to pain medication

1 - such as the stepped approach of the World Health
2 Organization's pain relief ladder for cancer - has been
3 considered a human right under international law since the
4 1961 adoption of the U. N. Single Convention on Narcotic
5 Drugs. Do you see that?

6 **A.** I do.

7 **Q.** And is that -- is that consistent with your perspective
8 in terms of how the medical field views having prescription
9 opioids for appropriate cases?

10 **A.** It -- yes, it is.

11 **Q.** And then, if we go to the next paragraph, please, it
12 says in the United States, many pain experts agree that
13 physicians should prescribe opioids when necessary
14 regardless of outside pressure as an exercise of their moral
15 and ethical obligations to treat pain. Do you see that?

16 **A.** I do.

17 **Q.** Is that something you see within the course of your
18 career, that view among many physicians, that you should
19 prescribe prescription opioids where appropriate when
20 necessary as part of a moral and ethical obligation to their
21 patients?

22 **A.** Yes, it is.

23 **Q.** All right. Let's shift gears a little bit. I want to
24 now talk about treatments for pain and I'm going to touch on
25 prescription opioids in a minute, but before I do, I want to

1 talk about nonprescription opioid treatments for pain. Are
2 there treatments for pain that don't involve any kind of
3 medicine?

4 **A.** Yes, there are. Examples would be physical therapy.
5 Not involving medicine would include different
6 interventions, things like acupuncture, chiropractic
7 manipulation. There's some psychological treatments, things
8 such as teaching patients relaxation techniques, biofeedback
9 et cetera. So, short answer, there are.

10 **Q.** Do those types of treatments have limitations in terms
11 of addressing pain?

12 **A.** They do. There are some patients who are very much
13 benefited by them and, frankly, with those patients one
14 would likely be stopping there. And then there are other
15 patients who you try each and every one of those that seems
16 appropriate for their case and, unfortunately, it doesn't
17 work. It doesn't give them relief. It doesn't return their
18 function.

19 **Q.** When it comes to prescription medicines or just
20 medicines generally, before I turn to opioids, are there
21 other kinds of medicines that can be used to treat pain
22 other than prescription opioids?

23 **A.** Yes, there are. We use common anti-inflammatory
24 medications, Advil, Motrin, Aleve, things in that class.
25 So, nonsteroidal anti-inflammatories. We use muscle

1 relaxants.

2 There are groups of medications that are not opioids
3 that we use specifically to treat nerve pain. Those are
4 medications such as Neurontin. So, by trade name,
5 Neurontin, and Lyrica, and Cymbalta.

6 And then there's a whole host that are topical things
7 we have patients put on -- on the -- the Lidocaine patch,
8 for example.

9 **Q.** Are there limitations to those kinds of treatments?

10 **A.** Yes. Similar to what we just talked about, there are
11 some patients who get excellent relief from them and,
12 perhaps in many of those cases, one would stop there again.

13 There are other patients who don't get relief or can't
14 tolerate side effects. And then there are some patients
15 where there's a risk so you can't use those medications,
16 where it would be too dangerous to use those medications
17 given that person's specific medical history, accompanying
18 conditions, other medications they take.

19 **Q.** And I want to just pick up on an idea you alluded to.
20 You mentioned risks for some patients for those medications'
21 side effects. Do those medications carry their own distinct
22 risks that you have to take into account when deciding
23 whether to use them?

24 **A.** Yes. Those medications have their own risks that you
25 have to take into account and, frankly, essentially every

1 medication that a doctor prescribes has risks and benefits
2 and the job is to look at the individual patient in front of
3 you, take into account all of the information you have
4 available, weigh the risks and benefits of essentially any
5 medication that you're going to prescribe for that patient.

6 **Q.** Okay. So, I want to -- I want to turn from those
7 nonprescription opioid treatments to prescription opioids
8 and pick up on that concept that you were just talking about
9 in terms of benefits and risks and weighing those. In your
10 opinion, are there patients for whom the benefits of
11 prescription opioids outweigh the risks?

12 **A.** Yes, there are.

13 **Q.** And can you talk about why that is?

14 **A.** So, when we're weighing the risks and benefits of
15 opioid medications, a few things. One, we can get some
16 information about how high risk a given patient is for
17 developing addiction. If someone is at high risk for
18 developing addiction, they have a history of substance
19 abuse, they have a history of major untreated psychiatric
20 conditions such as bipolar, strong family history of
21 substance abuse, et cetera, would be at higher risk of
22 addiction.

23 There are other folks who we can identify as being very
24 low risk and there are other factors that come into it,
25 which is what's the patient's condition, the severity of it,

1 to what extent can non-opioid treatments get that patient
2 pain relief and return to function, and then to what extent
3 are those safe for that given patient. So, there's a whole
4 host of things that come into that risk benefit.

5 **Q.** That view you just expressed to us about the benefits
6 outweighing the risks for certain patients, do you
7 understand that to be the consensus of the medical community
8 when it comes to prescription opioids?

9 **A.** Yes, I do.

10 **Q.** Do you have an understanding as to whether that
11 consensus is reflected in the fact of FDA approval of
12 prescription medicines?

13 **A.** Yes. I think that the FDA approval of those
14 medications reflects a consensus that for certain patients,
15 for selected patients' judicious use, the benefits outweigh
16 the risks.

17 **Q.** I would like to talk a little bit more about, first,
18 the risks of prescription opioids and then some of the
19 benefits. And to do that I want to use as an illustration
20 point something referred to as a label for a prescription
21 medicine or the prescribing information. Are you familiar
22 with that document for different prescription medicines, the
23 label, or the prescribing information?

24 **A.** Yes, I am. We also call it the package insert
25 sometimes.

1 MR. SCHMIDT: May I approach, Your Honor?

2 THE COURT: Yes.

3 BY MR. SCHMIDT:

4 Q. Doctor, I've handed you what we've marked as MCWV-1197,
5 which is a label for prescription medicine, and I will
6 apologize to all concerned in advance. We seem to have
7 found the smallest print copy possible of this document.
8 Fortunately, Mr. Reynolds can blow it up on the screen for
9 us.

10 If we could start in the upper left corner just to make
11 it large, it says Percocet (oxycodone and acetaminophen
12 tablets) C-II, controlled substance II, Schedule II,
13 prescription only. Do you see that?

14 A. I do.

15 Q. Are you familiar with -- from your work with this label
16 for Percocet, a prescription opioid?

17 A. Yes, I am.

18 Q. And just before we look a little bit at the contents of
19 this, what do you understand to be the purpose of a document
20 like this, the label, and who do you understand it to be
21 written for?

22 A. So, my understanding is that the purpose of the label
23 is in part for clinicians to tell them what's the
24 indication, which of the medications be -- what is it
25 indicated for, what's -- what are some of the risks of the

1 medication, something about the pharmacology, the contents
2 of the medication.

3 Specific things. You know, what you should do if the
4 patient has, for example, reduced kidney function with that
5 medication or interactions with other medications.

6 And then there's also some information that's directed
7 to patients and to their families in this.

8 **Q.** This version of the label has -- it says right below
9 the title we were looking at, it says revised July, 2018.
10 Do you see that?

11 **A.** I do.

12 **Q.** Do you have an understanding as to whether the label
13 for a given medicine is regularly and periodically updated
14 over time as new information becomes available?

15 **A.** My understanding is that they are, yes.

16 **Q.** And I want to pick up on something you were telling us
17 about in terms of some of the information. If we look at
18 this label, we see here there's a black box warning. And
19 then, if we scroll down below that past the black box
20 warning, please, it looks like there are different sections,
21 including some of the ones you mentioned.

22 We see something called the description of the
23 medication. Then, if we go to the next column, we see
24 pharmacokinetics, metabolism and elimination, something you
25 mentioned, indications and usage, contraindications,

1 warnings, et cetera.

2 And before diving into just a few of those sections, do
3 you have an understanding that what we're seeing here is
4 written according to a specified format in terms of these
5 different sections and what's supposed to appear, the types
6 of information that are supposed to appear in those
7 different sections?

8 MR. FARRELL: Objection, Your Honor. I'm not
9 quite sure that the doctor has been identified as an expert
10 in labeling.

11 MR. SCHMIDT: I think it's something he deals with
12 every day. If it's necessary, I can lay more of a
13 foundation but --

14 THE COURT: It seems to me that the labeling is
15 well within his field of expertise that I qualified him in.
16 So, I'm going to overrule the objection.

17 MR. FARRELL: Just to preserve for the record, I
18 don't have any problem with him testifying what's in the
19 label. What I have an objection to is I believe the
20 question of -- is what is his understanding of what the FDA
21 requires to be in the label.

22 BY MR. SCHMIDT:

23 Q. So --

24 THE COURT: I'm going to allow it. Overruled.

25 BY MR. SCHMIDT:

1 Q. Dr. Gilligan, from -- I'm not going to ask you -- we
2 haven't asked you to come here as an FDA expert, have we?

3 A. You have not, no.

4 Q. I'm going to ask you just some questions about this
5 label from your perspective as a physician. As a physician,
6 do you have occasion to consult with labels for a range of
7 different medicines and gather information from them?

8 A. Yes, I do.

9 Q. Does that require you to have basic information about
10 how they're formatted, at a high level, what goes into them?

11 A. Yes, it does.

12 Q. And so, when you look at different labels, do you see
13 that they have a specified format across different
14 medications with some of these sections we've been talking
15 about, warnings, indications, contraindications, and
16 specified information in those sections?

17 A. Yes. This is the typical type content and layout.

18 Q. And you heard reference to the FDA. Do you know
19 whether these labels are FDA approved?

20 A. Yes, they are.

21 Q. Is that relevant to you in your medical practice?

22 A. It's relevant to us because the information is useful
23 when you're prescribing these, you know, for all of the type
24 of topics that we've talked about. It informs your decision
25 to prescribe or not, and how to prescribe, what dose to

1 prescribe, et cetera, and it's -- it is important to us that
2 this language has been approved by FDA in terms of feeling
3 comfortable relying on it.

4 **Q.** Do you have the understanding that the companies that
5 manufacture these medicines are responsible for the contents
6 of these labels?

7 **A.** Yes. My understanding is that -- and my experience,
8 actually, is that there's a discussion between the company
9 and the FDA about what will be -- what will be agreed to go
10 into the label.

11 **Q.** And from your experience when this label sets forth the
12 -- well, let me just ask you a question. Without getting
13 into the substance here, what do you understand the
14 indications to tell you as a doctor?

15 **A.** So, it tells you what condition FDA has approved the
16 medication for use for.

17 **Q.** And then, obviously, what do you understand the
18 warnings to tell you?

19 **A.** That they want to make it quite clear to you what the
20 potential risks of the medication in question is, what the
21 medication -- what the specific identified risks of
22 whichever medication it may be are so that you know them and
23 can put them into that risk benefit balance that we talked
24 about.

25 **Q.** In terms of determining the substance of what this

1 label says, including who the medication might be
2 appropriate for, what the warnings that doctors need to
3 understand are, from your experience, do you know of any
4 role that wholesale distributors play in this content?

5 **A.** No. My understanding is they play no role in that.

6 **Q.** All right. So, let's look at the specific language.
7 And if we could go back to the first page to the black box
8 warning just to try to facilitate the structure here. It
9 says WARNING:, colon, in all caps, and then it lists a
10 series of conditions, addiction, abuse, and misuse.

11 And then it talks about a risk evaluation, mitigation
12 and strategy. And it looks like those conditions then
13 repeat with a little bit more information further down. Do
14 you see that?

15 **A.** I do.

16 **Q.** And so, I want to start with the warning about
17 addiction, abuse and misuse. Could you tell us what those
18 terms mean?

19 **A.** So, addiction is when a patient develops a compulsive
20 self-destructive craving to use -- essentially an out of
21 control use of -- of a substance and, in this case,
22 oxycodone. There are many substances, of course, that
23 people can get addicted to. So, it's a compulsive, and out
24 of control, and self-destructive use of a substance is
25 addiction.

1 THE COURT: Just a minute.

2 Mr. Ackerman?

3 MR. ACKERMAN: Your Honor, if I may, this document
4 is not in evidence, I don't believe, unless I missed
5 something. And so, I have an objection to displaying it on
6 the board.

7 MR. SCHMIDT: We'll move it into evidence, Your
8 Honor.

9 THE COURT: Any objection to it being admitted,
10 Mr. Ackerman?

11 MR. ACKERMAN: Hearsay.

12 MR. SCHMIDT: I think, at a minimum, it can come
13 in for the limited purpose of effect on doctors. It's
14 MCWV-1157.

15 THE COURT: I'll admit it for the limited purpose.

16 This is helpful to the Court and I -- I think that the
17 limit -- it's permissible for the limited purpose.

18 Go ahead, Mr. Schmidt.

19 BY MR. SCHMIDT:

20 **Q.** I think you had told us what addiction is. Can you
21 tell us what abuse and misuse are?

22 **A.** Sure. So, abuse and misuse, on the other hand, are
23 just taking the medication, we'd say, for a non-medical use;
24 in other words, taking the medication for the sake of
25 euphoria or whatever, whatever it may be, but not taking it

1 for a medical use to get -- to get pain relief. But someone
2 who is abusing or misusing a drug might be addicted, but
3 they also might not be addicted. They might just be abusing
4 and misusing it without having -- without -- being addicted.

5 **Q.** Under that heading it says Percocet exposes patients
6 and other users to the risks of opioid addiction, abuse, and
7 misuse, which can lead to overdose and death. Can you tell
8 us just at a high level what that's communicating to
9 doctors?

10 **A.** So, it's being very -- very clear to the doctors that
11 whether a patient develop -- if patients develop an
12 addiction or if they abuse or misuse the medication that
13 these medications can cause an overdose and that an overdose
14 can be deadly. And so, they are making that very starkly
15 clear.

16 **Q.** It continues to say assess each patient's risk prior to
17 prescribing Percocet and monitor all patients regularly for
18 the development of these behaviors and conditions. (See
19 warnings). Do you see that?

20 **A.** I do.

21 **Q.** Can you tell us what that's counseling doctors to do?

22 **A.** So, that's counseling doctors to do some of the things
23 that we talked about before of -- we call it opioid risk
24 stratification, of looking at all of the information that
25 you have about the patient in front of you; in many cases,

1 using their validated questionnaires that can help you to do
2 risk stratification so to make sure best informed
3 determination, is this patient high risk, medium risk or low
4 risk for addiction abuse and misuse if the doctor prescribes
5 opioid pain medications.

6 **Q.** And this reference here to see warnings, let's go back,
7 if we could, to the second column to that section we saw
8 briefly that says warnings. Is this a reference to further
9 information about addiction abuse and misuse?

10 **A.** Yes. It's expanding on that topic essentially.

11 **Q.** I want to go back to the black box warning, if we
12 could, and look at one more section. If we scroll down a
13 little bit there's also a heading on Neonatal Opioid
14 Withdrawal Syndrome. And then it has warnings about that
15 again with a cross-reference to the warnings section for
16 further information. Do you see that?

17 **A.** I do.

18 **Q.** We've heard in court about a condition called NAS. Is
19 that related to this condition?

20 **A.** Yes. It's essentially another way of saying -- saying
21 that same thing essentially.

22 **Q.** And if we go back up to the abuse, addiction and misuse
23 -- addiction abuse and misuse section, just to reemphasize
24 the point, in your experience, do these types of warnings
25 change over time and often become more developed over time?

1 **A.** Yes. In my experience, they do change over time and
2 they do have a tendency to become more developed, yes.

3 **Q.** In terms of these warnings we're focusing on now,
4 addiction, abuse and misuse, have you always understood
5 those to be a serious risk of opioid abuse throughout your
6 career and your medical training?

7 **A.** Yes, I have.

8 **Q.** And do you understand that to be a broad understanding
9 within the medical field?

10 **A.** Yes, I do understand it to be a broad understanding
11 throughout the field of medicine.

12 **Q.** Does that knowledge of the risk of addiction, abuse,
13 misuse impact how you prescribe opioids?

14 **A.** Yes, very much so, because it's -- again, with opioid
15 prescribing or all medications it boils down to largely risk
16 versus benefit and, as a key risk, that's a very significant
17 factor in your decision to prescribe or not and, if you do
18 prescribe, what to prescribe, how much to prescribe, how
19 long to prescribe, et cetera.

20 **Q.** Can addiction be an extremely serious condition?

21 **A.** Addiction can be a fatal condition.

22 **Q.** Does the risk in your experience and from your
23 understanding of the science vary across patients you might
24 see?

25 **A.** I'm sorry. Can you repeat the question, please?

1 **Q.** Yes. I'm sorry. Does the risk from your experience
2 vary across the range of patients you see, the risk of
3 addiction and abuse and misuse?

4 **A.** Yes. The risk of addiction, abuse and misuse varies
5 quite significantly across patients.

6 **Q.** And can you give us a little more information as to how
7 that's so?

8 **A.** Sure. So, we talked already about that there are
9 validated risk stratification questionnaires that you can
10 use with patients. There are also characteristics. And
11 those are some of the things we talked about of a personal
12 history of substance abuse, a family history of substance
13 abuse, a major psychiatric condition, such as Bipolar
14 Disorder, ADHD.

15 There are also some just demographic factors, age,
16 gender can play into it, so that you can -- you can say not
17 with perfect accuracy, but with very meaningful information
18 one patient is very at high risk. One patient is medium
19 risk. And one patient is low risk. And you can even
20 identify somebody who might be very, very low risk.

21 **Q.** And in your experience in your career, you've kind of
22 touched on steps you take with your patients to try to weigh
23 that risk and benefit on an individual patient basis.

24 Taking those steps, can you comment on how common -- how
25 common that you've seen addiction in the patients you treat

1 with prescription opioids?

2 **A.** So, for the patients who I have initiated the opioids,
3 I have not seen a patient who has developed addiction. I
4 have treated patients who were referred to me by other
5 physicians who were on opioids who have developed addiction
6 and misuse and abuse.

7 MR. SCHMIDT: And I apologize. May I approach,
8 Your Honor?

9 THE COURT: Yes.

10 MR. SCHMIDT: I've been sitting up here drinking.
11 I don't know if this is your water. Oh, it is? Okay. I'll
12 give you one more just in case.

13 THE WITNESS: Thank you.

14 BY MR. SCHMIDT:

15 **Q.** Just to go back to that last answer you gave me about
16 how rare it is in your practice, how do you know that's true
17 in terms of how do you know you're not seeing addiction that
18 you just don't hear about?

19 **A.** So, that certainly could be possible, but we're the
20 largest healthcare system in Massachusetts and we have one
21 single computerized medical record where we can see all of
22 the tests, all of the notes, et cetera.

23 And so -- and if a patient does develop a problem with
24 addiction, it's highly, highly likely that over time they
25 will have an encounter with the healthcare system related to

1 that. And since we're the biggest healthcare system in
2 Massachusetts and have a single computer record that we see
3 and that we monitor our patients, we see them monthly if
4 they're on opioids, we follow urine toxicology, et cetera.
5 We monitor them closely.

6 I think it would be extremely unlikely that one of my
7 patients would develop addiction and that I would not be
8 aware of it.

9 **Q.** I want to just finish up with some questions about this
10 prescribing information, this label, and then dive into one
11 specific aspect of abuse and misuse with you. I've been
12 referring to this as a black box warning. Do you know what
13 that is from your medical practice?

14 **A.** Yes. From a doctor's point of view a black box warning
15 is -- not all medications have a black box warning and the
16 FDA puts on the label of certain medications a black box
17 warning when they feel there's a specific serious risk that
18 they want doctors to be particularly aware of, so they put a
19 black box around it.

20 We know to look for that, to take it seriously, and
21 they typically put it, in my experience, at the front of the
22 label, again, to emphasize it to clinicians.

23 **Q.** One more question on this label. If we go to the
24 second to last column, or third to last column, I apologize,
25 it says medication guide. Percocet. And then it's got an

1 explanation of what Percocet is that reads a little more
2 common sense than the language we were looking at before.
3 Can you tell us what a medication guide is, to your
4 understanding, what it's intended for?

5 **A.** So, a medication guide is aimed at the patient or the
6 patient's family members; whereas, the other portion was
7 aimed at clinicians, doctors, et cetera, the medication
8 guide is aimed in more -- in simpler language. So, aimed at
9 the patient, or the patient's family members, or associates.

10 **Q.** And just focusing on these two bullets, it says
11 Percocet is, and then, one, a strong prescription pain
12 medicine that contains an opioid narcotic that is used to
13 manage pain severe enough to require an opioid analgesic and
14 for which treatments are inadequate and when other pain
15 treatments such as non-opioid pain medicines do not treat
16 your pain well enough or you cannot tolerate them.

17 Is that talking about where the medicine is supposed to
18 be used?

19 **A.** That's exactly what it's doing, yes.

20 **Q.** It then says an opioid pain medicine that can put you
21 at risk for overdose and death. Even if you take your dose
22 correctly as prescribed, you are at risk for opioid
23 addiction, abuse and misuse that can lead to death. Do you
24 see that?

25 **A.** I do.

1 **Q.** And, again, just recognizing that these documents
2 change over time, is it your understanding that that's what
3 this medication guide now tells patients?

4 **A.** That is my understanding, yes.

5 **Q.** All right. That's what I wanted to cover with you on
6 that document.

7 I want to switch gears a little bit and pick up on a
8 concept that we've heard about, we've sometimes heard
9 referred to as gateway. In your experience, are there
10 patients you know of or individuals you know of who have
11 misused prescription opioids at one point in time and then
12 later misused heroin?

13 **A.** Yes, there are.

14 **Q.** Can you comment on how common that is in patients you
15 have treated?

16 **A.** So, that's been -- that's been quite rare in patients
17 I've treated. For example, that has not happened a single
18 time in a patient where I -- that I'm aware of in a patient
19 that I initiated opioids, but I have seen it happen in
20 patients who I have been involved in the treatment where
21 other -- other physicians had initiated the opioids.

22 **Q.** Are you aware of scientific literature that speaks to
23 that question and tries to analyze that question?

24 **A.** Yes, I am.

25 **Q.** I want to show you one article on that as an example,

1 DEF-WV-2331.

2 MR. SCHMIDT: May I approach, Your Honor?

3 THE COURT: Yes.

4 Q. Is this an article -- the lead author is Muhuri,
5 M-u-h-u-r-i -- that you have reviewed in connection with
6 your medical practice and in the context of your work in
7 this case?

8 A. Yes, it is.

9 Q. Let's start with the title. The title says
10 Associations of Non-Medical Pain Reliever Use and Initiation
11 of Heroin Use in the United States.

12 So, I want to just break that down for a little bit.
13 That reference to the word associations, do you have an
14 understanding of what an association is?

15 A. Yes. That statistically, do the two things go
16 together? What's the rate with which they go together?

17 Q. From your understanding of medical literature, does the
18 fact that two things statistically go together mean you know
19 there's causation from one to the other?

20 A. No, it does not.

21 MR. ACKERMAN: Your Honor, just with respect to
22 displaying the document on the board during our -- the
23 plaintiffs' case, we were precluded from putting documents
24 on the board that had not been admitted into evidence. So,
25 I assume that same rule applies with respect to defendants.

1 They objected on numerous occasions to our attempts to put
2 documents on the board.

3 THE COURT: Well, I --

4 MR. SCHMIDT: I think that's gone both ways, but
5 this is a medical treatise.

6 THE COURT: I'm sorry, Mr. Schmidt.

7 MR. SCHMIDT: I talked over the Court. I
8 apologize.

9 THE COURT: Well, you were very rarely precluded
10 from displaying the documents. It was -- it was whether
11 they could be -- as I recall, whether they could just be
12 displayed before the witness testified, but I consistently
13 allowed you to display documents during the -- to illustrate
14 the witness's testimony, as I recall.

15 MR. ACKERMAN: With respect, Your Honor, I think
16 there were numerous witnesses where defendants objected to
17 us putting documents on the board. Personally, I put up Dr.
18 Mohr. Defendants objected in entirety to us putting
19 documents on the board and we were not permitted to do so.

20 Of course, it's within the discretion of the Court, but
21 I want to make sure that objection is stated for the record.

22 THE COURT: Well, this is technical and
23 complicated testimony and it's helpful to the Court to have
24 these documents available. I'm going to overrule the
25 objection and let you go ahead.

1 MR. SCHMIDT: Thank you, Your Honor.

2 BY MR. SCHMIDT:

3 Q. So, sticking with the title, it refers to something
4 called Non-Medical Pain Reliever Use and then, just for ease
5 of tracking, it defines that down below as NMPR, non-medical
6 pain reliever use. What is that?

7 A. So, non-medical pain reliever use is when a patient
8 takes an opioid pain medication but doesn't take it for a
9 medical reason, doesn't take it for relief of pain, takes it
10 essentially in the categories we talked about of abuse,
11 misuse, et cetera. So, if they're taking a prescription
12 opioid, but they're taking it to misuse or use it, they are
13 not taking it to treat a medical condition.

14 Q. So, just to be clear I have that, when this article is
15 looking at associations between pain reliever use and
16 heroin, is it looking at people who are using their
17 medicines as prescribed or misusing prescription opioids?

18 A. It's specifically looking at patients who are misusing
19 the prescription opioids.

20 Q. And do you have an understanding as to whether that's
21 the focus of the medical literature in this area when it was
22 looking at the link between prescription opioids and heroin,
23 it was focusing on misuse of prescription opioids?

24 A. That's my understanding, yes.

25 Q. Let's look at the abstract, the summary of the study,

1 and if we could look a little further down, there's a
2 reference that says pooling data from the National Survey on
3 Drug Use and Health, and it summarizes that as NSDUH,
4 conducted annually from 2002 through 2011. Do you see that
5 reference, the data source for the study?

6 **A.** I do.

7 **Q.** Are you familiar with that data source?

8 **A.** Yes, I am.

9 **Q.** Could you just give us at a high level what it is?

10 **A.** So, it's a large national survey that tries to track
11 the rate of drug use, abuse, misuse, et cetera, among
12 Americans.

13 **Q.** And then the sentence finishes, the study finds that
14 the recent 12 months preceding interview heroin incidence
15 rate was 19 times higher among those who reported prior
16 non-medical pain reliever use -- and if we scroll down just
17 a little bit -- then among those who did not, and it gives
18 the statistics, .39 versus .02 percent. Do you see that?

19 **A.** I do.

20 **Q.** And if we scroll a little further down in the abstract,
21 it says --

22 MR. SCHMIDT: And can you actually get us the
23 sentence before, as well, Mr. Reynolds? Is that possible?
24 Oh, wonderful.

25 BY MR. SCHMIDT:

1 Q. It says, however, the vast majority of NMPR,
2 non-medical pain reliever users, have not regressed to
3 heroin use. Only 3.6 percent of NMPR initiates had
4 initiated heroin use within the five-year period following
5 first NMPR use.

6 At the risk of asking you to state the obvious, can you
7 tell us what this 3.6 percent figure indicates?

8 A. Sure. So, their finding is that for patients who
9 started misusing, abusing non-medical pain reliever,
10 abusing, misusing opioid pain medications over the
11 subsequent 5 years, 3.6 percent of those people did then go
12 on to initiate heroin use and the remainder did not.

13 Q. Okay. So, I'm going to -- if I may, I'm going to ask
14 you about two sets of statistics from this study. The first
15 is the one we just talked about. And I want to make sure I
16 have this right. That 3.6 percent figure, does that address
17 people who misuse prescription Rx opioids and go on to use
18 heroin?

19 A. Yes, it does, over the subsequent five years.

20 Q. And just -- you might still have the publication in
21 front of you. Can you tell us again, just from the board,
22 what that percentage is of the people who misuse
23 prescription opioids and go on to use heroin?

24 A. 3.6 percent.

25 Q. Are you aware of whether the study also looks kind of

1 at it from the other end of the spectrum, among the people
2 who used heroin, how many of them have previously misused
3 prescription opioids?

4 **A.** Yes. So, it's about 80 percent of the people who used
5 heroin had previously misused or abused prescription
6 opioids. I think it's 79. -- 79.5 percent.

7 **Q.** Okay. That's where I'll go to next. So, just so we
8 have it clear for the record, on the right-hand side of the
9 board we have the number of people who misuse prescription
10 opioids and go on to heroin, and that's 3.6 percent. And
11 then, on the left-hand side of the board, we have the people
12 who use heroin. What have they previously used? That's
13 what I'm going to ask you about, okay?

14 **A.** Okay.

15 **Q.** And you've already told us about this, but is there
16 data in this study on that question?

17 **A.** There is.

18 **Q.** So, let's look at that data. Probably the easiest way
19 to do it is to go to Page 11, please. And if we look at
20 Page 11, Table 3 is entitled Percentage Distribution of Past
21 Year Heroin Initiates aged 12 to 49. And let me just pause
22 there.

23 Is this telling us, actually, by demographic and
24 geographic characteristics and prior illicit drug use
25 status? Do you see that?

1 **A.** I do.

2 **Q.** Is this giving us data looking at people who have
3 started heroin between 12 and 49 in the past year and some
4 of their characteristics?

5 **A.** Yes. That's exactly what it's telling us.

6 **Q.** And if I look at this table, at the top in the orange
7 or red area, it says Percent Distribution. And then it's
8 got different time intervals, 2002-2004, et cetera, all the
9 way up to a full range of years, 2002-2011. Do you see
10 that?

11 **A.** I do.

12 **Q.** And I'm going to focus on the full range of years. I'm
13 not sure it's materially different, but let me just capture
14 the fullest dataset, 2002-2011, and I want to show the Court
15 that statistic you were talking about.

16 So, if we stay on that far right column and go all the
17 way down to the bottom of the page, do you see at the bottom
18 of the page they break the group of heroin users they
19 surveyed out between those who had no prior non-medical pain
20 reliever use and those who had prior medical pain reliever
21 use?

22 **A.** I do, although it's prior non-medical pain reliever
23 use.

24 **Q.** Oh, I might have misspoke. Okay, sorry. And do you
25 see the statistic you told us about in terms of the

1 percentage of patients who -- the percentage of people who
2 -- I'm sorry. Let me start my question again.

3 Can you tell us the statistic in terms of the number of
4 people who used heroin in the last year and then, at some
5 point prior to that, had non-medical pain reliever use?

6 **A.** Yes. So, 79.5 percent of the people in this age group
7 who initiated heroin use in the -- in the leading to -- in
8 the prior 12 months, 79.5 percent of them had engaged
9 previously in non-medical pain reliever use.

10 **Q.** Okay. Is that the same as misuse of prescription
11 opioids?

12 **A.** That's the same as misuse and abuse of prescription
13 opioids.

14 **Q.** Is that a meaningful statistic?

15 **A.** Yes, it is.

16 **Q.** We see in this study that it is using data up through
17 2011 according to the heading. Have you considered -- have
18 you continued to see data like this published more closely
19 in time to today?

20 **A.** Yes, I have.

21 **Q.** Broadly speaking, do you know whether this number has
22 stayed the same, gone up, gone down?

23 **A.** Broadly speaking, that number actually has gone down.
24 There are more of the people who have initiated heroin use
25 who actually have not previously misused or abused

1 prescription opioids in more recent times.

2 **Q.** Okay. So, I want to stick with this portion of the
3 article we have up on the screen and under the heading we've
4 been talking about --

5 **MR. SCHMIDT:** And, Mr. Reynolds, I think you've
6 actually got the wrong percentage highlighted. It should be
7 the bold 79.5 percent.

8 **BY MR. SCHMIDT:**

9 **Q.** Under the heading that tells us prior NMPR use and then
10 we see 79.5 percent, the number we have up on the board, do
11 you see that?

12 **A.** I do.

13 **Q.** In the sub-columns do you see the reference to prior
14 illicit drug use?

15 **A.** I do.

16 **Q.** All right. And I want to ask you what that means and
17 then ask you what that data tells us. Do you see the little
18 footnote marker number 2 there?

19 **A.** I do.

20 **Q.** If we turn to Page 12 of the article, do you see that
21 it defines what Footnote 2 is, what illicit drugs are?

22 **A.** I do.

23 **Q.** And could you just read into the record what those are?

24 **A.** So, it says illicit drugs include marijuana, hashish,
25 cocaine, including crack, hallucinogens and inhalants.

1 **Q.** So, I've written on the board marijuana, cocaine,
2 crack, other illegal drugs. And so, having that on the
3 board --

4 MR. SCHMIDT: If we could go back to the bottom of
5 Table 3 on Page 11 of the document, please.

6 BY MR. SCHMIDT:

7 **Q.** Under the bold heading Prior Non-Medical Pain Reliever
8 Use, Prior Misuse of Prescription Opioids, do you see where
9 they break out people who had no prior illicit drug use and
10 people who did have prior illicit drug use?

11 **A.** I do.

12 **Q.** And can you tell us from looking at that data what
13 percentage of heroin users in this study had both prior
14 non-medical pain reliever use and prior illicit drug use?

15 **A.** So, for prior illicit drug use, it's 79.5 percent.

16 **Q.** And then, I want to look at the heading above, looking
17 at the patients who have no prior non-medical pain reliever
18 use. Do you see that heading?

19 **A.** I do.

20 **Q.** And do you see below that where it tells us the
21 patients -- the percentage of the pool who have no prior
22 non-medical pain reliever use, but who have prior illicit
23 drug use, what percentage that is?

24 **A.** That's 19.4 percent.

25 **Q.** I'm going to ask you what I hope is my toughest

1 question. I've already shown myself today to be unreliable
2 at math.

3 Can you tell us what these two numbers add up to in
4 terms of the number of heroin users who have some prior
5 illegal drug use?

6 **A.** So, 98.9 percent.

7 **Q.** So, a couple questions about that data and how it
8 meshes with your experience. First of all, this article
9 gives us data on people who misuse prescription opioids. It
10 gives us data on people who misuse illegal drugs like crack
11 cocaine and cocaine and other drugs. Are there other
12 factors relevant to substance abuse that may or may not be
13 reported in this article, may not be captured in this data?

14 **A.** Yes, there are.

15 **Q.** Could you speak with us about some of those factors?

16 **A.** So, those are the factors that we talked before of a
17 family history of substance abuse, major psychiatric
18 illnesses such as Bipolar Disorder, et cetera, even
19 demographic factors, age, gender, et cetera, et cetera, that
20 predispose somebody to be at risk for substance abuse,
21 misuse, et cetera. Those factors apply here, as well as the
22 statistics that we're talking about.

23 **Q.** Now, focusing on these two numbers here and drawing on
24 your medical experience and your understanding of the
25 science, are you able to say whether of these people who

1 used heroin, who had previously misused prescription
2 opioids, whether if you took away that prescription --
3 misuse of prescription opioids, but still had the other
4 factors, the 98.9 percent who are abusing illegal drugs and
5 then the other factors you just alluded to, whether that
6 would change the heroin rates, do you know?

7 **A.** You can't say.

8 **Q.** And why is that?

9 **A.** Because even if you took away the misuse and abuse of
10 the prescription opioids, all of those other risk factors,
11 there are folks who already are engaged, 98.9 percent of
12 them, in use abuse, misuse of illicit substances. So, by
13 definition, they're engaged in that and would be at risk of
14 additional substance abuse, including heroin abuse and
15 misuse.

16 **Q.** Can you say looking at this data whether this is a
17 problem that's isolated to the misuse of prescription
18 opioids, as opposed to a broader substance abuse problem?

19 **A.** So, it's a broader substance abuse problem where, in
20 some patients or in some individual's case there is misuse
21 and abuse of prescription opioids, but it's a broader
22 substance abuse problem.

23 **Q.** Let's conclude with that topic. I want to go back to
24 what we were talking about in terms of benefit and risk.
25 We've spent a lot of time talking about risk, pretty serious

1 risk. Given those risks of prescription opioids, why is it
2 that doctors still use prescription opioids?

3 **A.** So, the reason that doctors still use prescription
4 opioids despite those risks that we've talked about, which
5 are significant, is that they're our most potent pain
6 medications and there are some cases where patients have
7 severe disabling pain that we can't treat successfully
8 and/or safely with non-opioid treatments.

9 And so, there's some patients where it clearly does add
10 up in terms of risk benefit to treat them with the opioids
11 and, as we talked about before, there's some patients where
12 those risks we can identify as being substantially lower for
13 that patient. So, in the end, that risk benefit does fall
14 squarely on using opioids to treat that patient's case.

15 **Q.** You talked earlier about your clinical research, your
16 scientific research. Have there been efforts in the
17 scientific community over time to come up with alternatives
18 to prescription opioids that would be as effective at
19 treating pain without having these risks we've been talking
20 about?

21 **A.** Yes. Identifying a very powerful non-opioid pain
22 medication that's safe and has no risk of addiction has
23 essentially been a holy grail of our field.

24 **Q.** Have pain management found that holy grail?

25 **A.** Not -- not yet.

1 **Q.** Okay. Let me talk about data for a little bit on
2 prescription opioids. Are you familiar --

3 THE COURT: Is this a good place to stop? It's
4 about break time, Mr. Schmidt.

5 MR. SCHMIDT: Sure. Yeah. Yeah.

6 THE COURT: Let's be in recess for about ten
7 minutes.

8 You can step down, Dr. Gilligan.

9 THE WITNESS: Thank you, Your Honor.

10 (Recess taken)

11 (Proceedings resumed at 10:37 as follows:)

12 THE COURT: When you're ready, Mr. Schmidt.

13 MR. SCHMIDT: Thank you, Your Honor.

14 BY MR. SCHMIDT:

15 **Q.** Dr. Gilligan, I want to pick up with where we were
16 by talking about the benefits of these medicines.

17 You talked a little bit about the search for
18 alternatives. And I wanted to talk to you a little bit
19 about, in broad terms your understanding of the data
20 regarding these medicines.

21 Are you aware of studies showing that opioids are
22 effective for treating acute pain?

23 **A.** Yes, I am.

24 **Q.** And what -- can you speak to what the data shows in
25 terms of using prescription opioids to treat chronic pain?

1 **A.** So for chronic pain, the data with chronic opioid
2 therapy is, frankly, more mixed. There are studies that
3 show that if you use chronic opioid therapy for non-cancer
4 pain cross a population in the study, in some studies that
5 you don't see an improvement in function, or even a subset
6 is you don't see an improvement in pain. Some show
7 improvement. Some don't. And the studies show high rates
8 of harm, of adverse effects from chronic opioid therapy for
9 non-cancer pain.

10 **Q.** So does that mean that doctors today never use
11 prescription opioids for chronic non-cancer pain?

12 **A.** No, it does not.

13 **Q.** So can you explain that -- can you reconcile that for
14 us? Why are doctors using it if the study data is mixed?

15 **A.** So if the study data is showing across a population in
16 a study you're not seeing an improvement in function, in
17 some cases in pain in many of those studies, but there are
18 certain individual patients who do do very well.

19 So it's the difference between an individual patient if
20 you select someone who has low risk for developing problems
21 with addiction who has a condition that you're being very
22 selective, the indication for using it for that condition is
23 really quite strong and the benefit, or the potential
24 benefit for that patient is quite high. It's the difference
25 between there are some individual patients who do very well

1 versus what you see when you look at a population in a study
2 on average.

3 **Q.** Do you understand that view you just expressed that
4 there are individual patients for whom prescription opioids
5 are appropriate for chronic non-cancer pain, do you
6 understand that view to be the consensus of the medical
7 community?

8 **A.** Yes, I do.

9 **Q.** For example, are you familiar with CDC guidelines that
10 have come out in the last several years regarding the use of
11 prescription opioids in chronic non-cancer pain?

12 **A.** Yes, I am.

13 **Q.** And do they allow for or recognize that for some
14 patients using prescription opioids for chronic non-cancer
15 pain is appropriate?

16 **A.** They do. They spell out what are the circumstances
17 where it would be appropriate to do it. They spell out how
18 to do it judiciously and cautiously. They spell out
19 guidance on what types of doses to use, et cetera, how to
20 monitor patients.

21 But the whole point of those guidelines implicit in
22 them is that they are giving you guidance on when and how to
23 appropriately use opioid pain medications for chronic
24 non-cancer pain.

25 **Q.** Dr. Gilligan, there's been discussion in the case

1 about -- a little bit of discussion in the case about
2 prescribing levels of opioids in the United States versus
3 other countries.

4 Do you have experience in your medical practice with
5 use of prescription opioids in countries where they're much
6 more restricted and conservative in using prescription
7 opioids?

8 **A.** I do.

9 **Q.** Can you tell us about that experience?

10 **A.** Sure. So in one of my roles at the Brigham is that I'm
11 the Medical Director for an affiliation that we have with a
12 cancer hospital in China. And in China, the use of opioids
13 for cancer pain and for non-cancer pain is far, far more
14 conservative than it is in the United States.

15 **Q.** And how do you see that play out in your experience in
16 terms of patient care?

17 **A.** So there are some patients who we see there who --
18 their pain is -- could be safely and much more effectively
19 controlled if opioids were used in their cases and in the
20 way that we would use it; in other words, cautiously
21 judiciously but appropriately.

22 We see some patients who in our judgment are, for
23 example, dying of cancer and suffering from very, very
24 severe pain that we think could be more effectively and
25 safely treated with opioids.

1 **Q.** We've been talking about the risks and benefits of
2 opioid medications. Do you have a view as to who in the
3 healthcare system is best situated to counsel patients on
4 those benefits, on those risks?

5 **A.** I do.

6 **Q.** Who is that?

7 **A.** I think clinicians, principally doctors, because our
8 education is to have abundant knowledge about the conditions
9 and the medications and their risks and the potential
10 benefits.

11 Our training is training us to make those judgments,
12 how to take in that information and take it in, weigh in,
13 you know, what's high quality information, what's low
14 quality information that you should tend to discount, et
15 cetera.

16 And then for these controlled substance prescription
17 medications, that's the, the authority that we get when we
18 get DEA certification, medical license, controlled substance
19 certificate, et cetera, that is both giving us that
20 authority to make a prescribing decision.

21 And the accompanying oversight bodies in our field are
22 also there for in case a physician stops prescribing
23 appropriately. And that can be at the level of the
24 hospital, at the Board of Registration of Medicine, could be
25 the DEA pulling somebody's certificate, et cetera.

1 So everything about our education, training, role,
2 authority, and then responsibility and monitoring is, is
3 matched to our role in making those decisions.

4 **Q.** I want to pull out some of those points you just walked
5 us through in a little more detail if I could.

6 Let me start with, with the first part of what you said
7 for us. In terms of access to medical records, access to
8 the patient, is, is there anyone or entity in the healthcare
9 system that has more visibility to the patient than the
10 doctor or other clinicians who's treating them?

11 **A.** No, there isn't because we're the one who's in the exam
12 room. We're taking the patient's complete relevant medical
13 history and demographic history, et cetera. We're examining
14 the patient. We're looking at the results of any relevant
15 test, X-rays, MRIs, lab tests, et cetera. The other -- at
16 least I can't think of another party that has that level of
17 information specific to that patient.

18 **Q.** Uh-huh.

19 **A.** And these decisions are all about the individual
20 details of that individual patient's case. That's the
21 essence of, of making those decisions appropriately and
22 correctly in individual cases.

23 **Q.** As a physician, are you bound by both legal
24 responsibilities regarding your patient and ethical
25 responsibilities?

1 **A.** Yes, we are.

2 **Q.** And do you have a view whether it would further those
3 legal and ethical responsibilities if you were caring for
4 your patients and making judgments for your patients other
5 participants in the healthcare system like distributors were
6 second-guessing those judgments?

7 **A.** I, I don't think that that would be helpful for our
8 patients. I don't think that would be helpful for society.
9 I do not think that that would help to make the decisions be
10 done more appropriately.

11 **Q.** You, you talked about some consequences in your answer
12 a few moments ago for doctors who don't practice within
13 those standards. You were talking about including losing
14 their ability to practice, maybe going to jail. And we've
15 heard some examples of that.

16 But short of losing a license or criminal action, are
17 there other controls in your experience that apply to
18 doctors who are inappropriately prescribing?

19 **A.** Yes, there are.

20 **Q.** Can you tell us about some of those?

21 **A.** So when we have concerns within our healthcare system
22 about a physician's prescribing, we'll step in and we'll
23 monitor that physician's prescribing. We will, for example,
24 pull 25 charts per month from that patient, that physician's
25 patients and review those records and look at the records

1 and say were the prescribing decisions in each of those
2 cases made appropriately or not.

3 We'll do didactic education sessions sometimes one on
4 one with that physician and other things along those lines.

5 **Q.** And you just in giving that answer referred to yourself
6 in the first person plural. Have you been involved in that
7 kind of review of other physicians' prescribing practices so
8 you can make judgments about whether it's appropriate or
9 inappropriate?

10 **A.** Yes, I have.

11 **Q.** Is that something you're able to do just by looking at
12 prescribing records and prescribing levels or, or do you
13 need more patient information?

14 **A.** When I do that and when we do that in general, we need
15 the patient level information because you can't determine if
16 a given prescribing decision was appropriate or not unless
17 you get the relevant information; in other words, what was
18 the patient's history, what were the findings on exam, what
19 did the tests show, what other therapies were tried, et
20 cetera, to make that determination about that case.

21 **Q.** Okay. Does making that determination require you to
22 exercise medical judgment based on your medical training?

23 **A.** Yes, it does.

24 **Q.** I'm going to turn to our last topic. It's a larger
25 topic. It might take us close to lunch or just shy of

1 lunch. And it's, it's a concept that we've heard referred
2 to as standard of care. Is that a concept you're familiar
3 with in medical practice?

4 **A.** Yes, it is.

5 **Q.** Can you tell us what that means in terms of medical
6 practice?

7 **A.** So standard of care in medical practice means the
8 quality of care, the thoroughness, the safety of care that
9 doctors expect to maintain in his or her fields. Sometimes
10 there's a geographic component to it, you know, in
11 practicing in your field and in the area where you practice,
12 what you would be expected to do. And that can apply to
13 anything. That can apply to the -- what you should be
14 expected to have done if somebody came in with a potential
15 heart attack.

16 **Q.** I want to focus on prescription opioids. Are you aware
17 of whether the standard of care regarding prescription
18 opioids has changed over the past several decades?

19 **A.** Yes, it has.

20 **Q.** And at a high level can you walk us through that
21 change?

22 **A.** So in the period around the 1990s in particular, a
23 little bit in there, 1980s as well, there was an emphasis on
24 the concept that we were under-treating pain in this country
25 and that we were placing too much emphasis -- that we were

1 exaggerating, would have been the argument, the potential
2 risks of opioids, that we were under-utilizing them and we
3 were leaving too many patients with pain that could have
4 slash should have been treated with opioids.

5 Then as prescribing went up by about certainly I think
6 roughly the mid 2000s, there was much more awareness of the
7 adverse effects and the argument that perhaps we were
8 prescribing too many opioids as opposed to too few, and that
9 we were -- that we should put more emphasis on the potential
10 risks of the medication.

11 Then around 2011 prescribing in the country peaked and
12 started to go down. And since then, there's been
13 significant emphasis on the, the risks of these medications,
14 potential risks, the fact that there are some patients with
15 chronic non-cancer pain, for example, who don't get
16 significant benefit where -- while there are some people who
17 do.

18 And, so, an emphasis on still using the medications but
19 being more conservative about them as part of the standard
20 of care.

21 **Q.** Okay. We, we've heard evidence in this case about
22 prescribing rates in Cabell County, West Virginia. And I
23 want to just ask you if that's consistent with what you just
24 told us.

25 The evidence is prescribing rates increased in the late

1 '90s up until a peak in about, between 2010, 2012, that
2 range, and then have gone back down. Is that consistent
3 with those changes in the standard of care that you told us
4 about?

5 **A.** Yes, it is.

6 **Q.** Is it consistent with your understanding of national
7 prescribing trends in terms of increasing from the '90s up
8 until sometime in the 2010, 2012 window and then coming back
9 down?

10 **A.** It is.

11 **Q.** All right. I'd like to show you some documents
12 relevant to the standard of care issue and the changes in
13 the standard of care that you talk about in your report.

14 Let me start, if I could, with MC-WV-1135.

15 MR. SCHMIDT: May I approach, Your Honor?

16 THE COURT: Yes.

17 MR. SCHMIDT: Thank you.

18 BY MR. SCHMIDT:

19 **Q.** And just to orient us, this is a publication from
20 the New England Journal of Medicine. Are you familiar
21 with that publication?

22 **A.** Yes, I am.

23 **Q.** It's dated January 14, 1982. Can you just characterize
24 for us the role that the New England Journal of Medicine
25 plays in the practice of medicine?

1 **A.** It's, it's one of the most respected medical journals
2 that there is.

3 **Q.** And if we look a little further down, there's an
4 editorial called "The Quality of Mercy." Do you see that?

5 **A.** I do.

6 **Q.** Are you familiar -- have you, have you read that
7 editorial that's actually attached there?

8 **A.** I have.

9 **Q.** If we go to Page 3 of the document -- we've skipped the
10 full journal but just focused on this editorial. It's
11 written by someone named Marcia Angell. Do you know if she
12 had a role at the New England Journal of Medicine at this
13 time?

14 **A.** Yes. She was a Deputy Editor at the New England
15 Journal at this time.

16 MR. SCHMIDT: Your Honor, we'd move this document,
17 MC-WV-1135, into evidence.

18 MR. FARRELL: Judge, this is a medical article,
19 medical literature, and I don't know that it's appropriate
20 to admit it into the record as evidence. And to the extent
21 that it's being offered for notice or some other reason, I
22 just don't think it's appropriate from the historical
23 rulings this Court has made about admitting medical
24 literature.

25 MR. SCHMIDT: Your Honor, just to be --

1 MR. ACKERMAN: Your Honor, may I add --

2 THE COURT: Yes.

3 MR. ACKERMAN: -- to my colleague's statement?

4 To the extent that defendants are relying on 803(18) as
5 the exception to the hearsay in the document, that exception
6 does not permit the admission of statements in a learned
7 treatise, but only permits that a statement in a learned
8 treatise may be read into evidence but not received as an
9 exhibit.

10 MR. SCHMIDT: Your Honor, just to orient the
11 Court, what we're actually moving it in under is 803(16),
12 16, statements in ancient documents, which I find that
13 expression a little hurtful. It's a statement in a document
14 that was prepared before January 1st, 1998, which this was,
15 and whose authenticity is established. And this is a
16 self-authenticating document under Rule 902(6).

17 MR. FARRELL: Judge, I vehemently object to the
18 reference of the year 1998 as being ancient.

19 MR. SCHMIDT: I join.

20 THE COURT: Well, you've got a point, Mr. Farrell.

21 MR. FARRELL: So, in general, Judge, I know this
22 article. We've talked about this article. I understand the
23 article. I support the article. I know the New England
24 Journal of Medicine is a leading text. And I also know the
25 point Mr. Schmidt is going to make.

1 I'm simply saying that we haven't been admitting
2 medical learned treatises into the record, but we have
3 liberally been using them and referencing them with experts
4 throughout this trial.

5 So I have no problem with referencing it or talking
6 about it. I'm looking forward to the testimony. I just --
7 I don't want to start the, the onslaught of admitting
8 medical literature as learned treatises or antiquities into
9 the record.

10 MR. SCHMIDT: I think the difference here is the
11 clear exception in Subsection (16). It's, it's pretty black
12 and white.

13 THE COURT: Well, --

14 MR. FARRELL: Perhaps, Judge, if it was offered
15 for the limited purpose of notice or limited purpose,
16 something other than a learned treatise because if we're
17 going to start admitting learned treatises, I have a book of
18 learned treatises and articles that we wish we would have
19 admitted during our case-in-chief.

20 MR. SCHMIDT: I think if they can come in under
21 803(16), they could do that. It's a pretty specific rule.

22 THE COURT: It's certainly admissible under
23 803(18) but it can't be admitted if -- we'd have to have him
24 read it if we did that.

25 MR. ACKERMAN: And, Your Honor, the part that

1 troubles me, and I will be frank with you that I never
2 looked into this, is how 803(16) could work to obviate what
3 appears to be a more applicable exception in 803(18).

4 MR. SCHMIDT: By its language, a statement in a
5 document that was prepared before January 1st, 1998, and the
6 authenticity is established.

7 THE COURT: Well, it comes within the literal
8 reading of (16), doesn't it, Mr. Ackerman?

9 MR. ACKERMAN: I think it does, Your Honor. I
10 don't dispute that.

11 THE COURT: I'm going to admit it under 803(16) --
12 BY MR. SCHMIDT:

13 Q. So let's --

14 THE COURT: -- for the truth of the matter
15 asserted.

16 BY MR. SCHMIDT:

17 Q. Let's look at Page 2, please, of this publication,
18 "The Quality of Mercy." You'll see that up there at the
19 top. And I just want to read a couple lines to you.

20 It says, "Few things that a doctor does are more
21 important than relieving pain."

22 Let me pause there. Is that a view you agree with
23 based on your medical practice?

24 A. Yes, it is.

25 Q. "Yet, the treatment of severe pain in hospitalized

1 patients is regularly and systematically inadequate."

2 Do you see that?

3 **A.** I do.

4 **Q.** And we're back in 1982 at this point in time. Was this
5 a view that started to be expressed in the medical
6 literature at this point in time?

7 MR. FARRELL: I'm going to make an objection,
8 Judge. If we're going to admit this, then we should admit
9 it for what it is. This isn't medical literature. I
10 believe this is an editorial.

11 MR. SCHMIDT: I'll rephrase.

12 BY MR. SCHMIDT:

13 **Q.** Is that a view that started to be expressed in the
14 medical community through various sources at this point
15 in time, that the treatment of severe pain in
16 hospitalized patients is regularly and systematically
17 inadequate?

18 THE COURT: Overruled. I'll let him answer that
19 question.

20 THE WITNESS: Yes, it is.

21 BY MR. SCHMIDT:

22 **Q.** It goes on to say -- it quotes some data. And then
23 in the sentence after quoting that data it says, "This
24 is not for want of tools. It is generally agreed that
25 most pain, no matter how severe, can be effectively

1 relieved by narcotic analgesics."

2 Do you see that?

3 **A.** I do.

4 **Q.** And, again, are you familiar with the point that there
5 started to be a movement in the medical profession to do
6 more to treat pain and recognized opioid analgesics as part
7 of that?

8 **A.** Yes.

9 **Q.** And, so, where I'm going to go with this --

10 MR. SCHMIDT: And I'm going to pass out the
11 completed version that we sent last night. We, we have
12 given counsel a demonstrative we're going to use. We'll
13 print out a copy, but you should have it from last night.
14 And we'll give out more when we're done. We're going to
15 build it with some of these articles.

16 Can we go to that please? I'm just going to track some
17 of these sources up on a board that we're going to see. And
18 I'm going to make a confession right at the outset. We had
19 trouble figuring out our timeline at the bottom.

20 So you'll see there's just years here along the bottom
21 and it's not to scale. We start with the '80s and then jump
22 all the way to the '90s and then kind of slow down a little
23 bit in the '90s.

24 But if you'll bear with me with that, I'm going to put
25 some of these up on the board.

1 So can we start by putting this article up on the
2 board?

3 BY MR. SCHMIDT:

4 **Q.** Is that that quote we were just looking at from the
5 New England Journal of Medicine about, "It is generally
6 agreed that most pain, no matter how severe, can be
7 effectively relieved by narcotic analgesics"?

8 **A.** It is, yes.

9 **Q.** All right. Let's go back to the article itself. We'll
10 come back to this board as we look at other publications and
11 documents.

12 If we scroll down into the next paragraph, it says,
13 "One consideration that limits the use of narcotics is the
14 possibility of a variety of side effects."

15 And then it lists several including drowsiness,
16 constipation, urinary retention and, most serious,
17 respiratory depression.

18 "A more important factor is a disproportionate
19 sometimes irrational fear on the part of the medical
20 profession and the public alike that patients will become
21 addicted."

22 Do you see that?

23 **A.** I do.

24 **Q.** And are you familiar with that view being expressed by
25 doctors at this point in time going forward that there might

1 be a disproportionate, sometimes irrational fear, on the
2 part of the medical profession and the public that patients
3 will become addicted?

4 **A.** Yes, that was one of the views that was being put forth
5 at that time.

6 **Q.** And let me just jump to the end of this article, if I
7 could, back to the author. I asked you earlier about Marcia
8 Angell. Is she someone who has standing in the medical
9 profession?

10 **A.** Yes. Dr. Angell was, was very respected.

11 **Q.** Did she have a reputation one way or another in terms
12 of her attitude towards drug companies and manufacturers?

13 **A.** Yes. She was well-known as really a fierce critic of
14 the for-profit pharmaceutical companies.

15 **Q.** Okay. Let's look at some other things that -- if we
16 could look at that paragraph you pulled up. It states, "It
17 is instructive to contrast the very low incidence of
18 important side effects with the very high incidence of
19 inadequate pain relief. I can't think of any other area of
20 medicine, in medicine in which such an extravagant concern
21 for side effects so drastically limits treatment. We are
22 used to a closer balance between risks and benefits."

23 Do you see that?

24 **A.** I do.

25 **Q.** And can you just comment on that statement,

1 particularly this statement at the end about risk and
2 benefits?

3 **A.** So Dr. Angell is making the point that we discussed
4 before that -- which was a point that was made at this time
5 period that the perception was we're not -- we weren't
6 treating pain aggressively enough and we were exaggerating
7 our understanding of the risks.

8 And, therefore, by definition then that would get your
9 risk benefit calculation off if you accept that argument.

10 **Q.** And then let's just go to the end of, of this article.

11 "Pain is soul destroying. No patient should have to
12 endure intense pain unnecessarily. The quality of mercy is
13 essential to the practice of medicine; here, of all places,
14 it should not be strained."

15 Do you see that?

16 **A.** I do.

17 **Q.** And how does that fit with your experience in pain
18 treatment and pain management?

19 **A.** I think actually she wrote that very, very well. I
20 think pain is soul destroying. I think that you wouldn't
21 want to see a pain -- a patient having to endure intense
22 pain unnecessarily. And I think that the quality of mercy
23 is essential to the practice of medicine.

24 **Q.** We've, we've walked through a series of statements in
25 this editorial. Is it meaningful if an editor at the New

1 England Journal of Medicine makes statements like this to
2 the medical profession?

3 **A.** Yes. This is a -- the New England Journal of Medicine,
4 as we've discussed, is one of the most respected medical
5 journals. Dr. Angell was a very well-known and respected
6 figure. And, so, a statement like this has a significant
7 impact on, on physicians.

8 **Q.** I'd like to approach with another document, if I may,
9 Defense West Virginia 3699. I've given you a copy of a
10 document entitled Cancer Pain Relief. And below the heading
11 you see a crest and it says it's from the World Health
12 Organization in Geneva. Do you see that?

13 **A.** I do.

14 **Q.** And then if we just flip ahead to the third page, it
15 again repeats the title, Cancer Pain Relief, World Health
16 Organization, 1986. Are you familiar -- are you familiar
17 with this document I've just handed you?

18 **A.** Yes, I am.

19 **Q.** Can you comment on the significance of this document in
20 pain management?

21 **A.** So this document was very, was very significant because
22 it's the document where the World Health Organization
23 introduced their cancer pain treatment letter which became
24 very well-known throughout medicine and, and had a very
25 significant influence on the practice of treating pain

1 across fields of medicine.

2 MR. SCHMIDT: Your Honor, we move into evidence
3 Defense West Virginia 3699 under the ancient documents
4 exception.

5 MR. ACKERMAN: I'd renew our objection, Your
6 Honor. I would just note that the Advisory Committee Note,
7 which Ms. Kearse has helpfully provided me, to Rule 803(16)
8 references letters, records, contracts, maps, and
9 certificates.

10 So I think -- again, it's our position that the ancient
11 document exception was not intended to apply to learned
12 treatises which are referenced in another section.

13 MR. SCHMIDT: The language, just for the record,
14 that's being referenced is, "Wigmore further states that the
15 ancient document technique of authentication is universally
16 conceded to apply to all sorts of documents." And then it
17 says "including the examples listed."

18 MR. RUBY: And, Your Honor, I know Mr. Schmidt
19 doesn't need my help, but with respect to Mr. Ackerman's
20 reference to the term "record," there are definitions, of
21 course, in the Rules of Evidence.

22 And in Rule 101(b)(4) record is defined to include a
23 memorandum or report which certainly would include this
24 document.

25 THE COURT: I'm going to admit it. It's admitted.

1 West Virginia 3699 is admitted.

2 BY MR. SCHMIDT:

3 **Q.** So let's look at what was important about this
4 document. And I'd like to, again, using the numbers in
5 the bottom left corner of the page, if we can go to Page
6 10, please. And there's a heading "Nature of Cancer
7 Pain." I'm actually going to look at the paragraph
8 right above that.

9 So now we're up to 1986. This tells us numerous
10 published reports indicate that cancer pain is often not
11 treated adequately.

12 Again, is that consistent with some of these
13 discussions from this time period now up to 1986 about doing
14 more to treat pain; in this case, cancer pain?

15 **A.** Yes, it is.

16 **Q.** "An analysis of 11 reports covering nearly 2,000
17 patients in developed countries," and they emphasize that,
18 "suggests that 50 to 80 percent of patients did not have
19 satisfactory relief. Many patients with advanced cancer and
20 moderate to severe pain are not given sufficient analgesic
21 medication to control their discomfort."

22 Are you familiar with that kind of data from this time
23 period showing that patients who had cancer pain weren't
24 given satisfactory relief?

25 **A.** Yes, I am.

1 **Q.** It says, "They are restricted to a weak opioid (e.g.
2 codeine) or a stronger drug is given on demand instead of
3 being given at appropriate regular intervals by the clock."

4 Then they talk about developing countries and that data
5 there.

6 And then the final sentence says, "It seems certain,
7 however, that most patients do not receive adequate therapy
8 because of legal and other constraints on access to drugs
9 and notably to the strong opioids."

10 Do you see that?

11 **A.** I do.

12 **Q.** And, again, was that a sentiment that was being
13 expressed at this time that legal and other constraints on
14 prescription opioids were depriving patients of effective
15 pain relief?

16 **A.** Yes. A constraint such as that and exaggeration of
17 concerns that we talked about from other, that was on other
18 documents were leading clinicians to under-use and --
19 under-use opioid pain medications and to under-treat pain.

20 And, essentially, the argument at that time was that
21 they -- clinicians were typically getting the risk benefits
22 wrong and not treating pain aggressively enough, not using
23 opioid pain medications enough.

24 **Q.** Let's go to Page 50, if we could, of this document. It
25 says, "Reasons for inadequate control of cancer pain."

1 And if you look at the -- I suppose it's the last
2 sentence here, it refers to a misconception by doctors,
3 nurses, and patients to the effect that physical dependence
4 and psychological dependence are interchangeable terms has
5 led to the under-use of opioid analgesics."

6 Do you see that?

7 **A.** I do.

8 **Q.** Is it meaningful when the World Health Organization is
9 making a statement like that about under-use of opioid
10 analgesics?

11 **A.** Yes, it's very meaningful.

12 **Q.** Okay. Let's go to the board, if we could, and we'll
13 just add that quote under use of opioid analgesics, 1986.

14 Why is it meaningful that the World Health
15 Organization, WHO, is saying what with reference to cancer
16 pain?

17 **A.** Because doctors know the World Health Organization.
18 You would be hard-pressed to find a doctor who doesn't know
19 the World Health Organization. And when they make a
20 statement that's that clear saying that we're under-treating
21 cancer pain and we should use opioids more often, more
22 aggressively to, frankly, do a better job of treating cancer
23 pain, that's a, that's a powerful statement coming from an
24 organization of that stature.

25 **Q.** Okay. Let's go back to the document. I want to jump

1 ahead now to Page 20.

2 And we see a heading on the side, on the page that says
3 "Drug Therapy." Do you see that?

4 **A.** I do.

5 **Q.** It says, "The use of analgesic drugs is the mainstay of
6 cancer pain management."

7 Does that remain true to this day?

8 **A.** That remains true to, to this day, yes.

9 **Q.** It says, "When used correctly, analgesics are effective
10 in a high percentage of patients. A three-step analgesic
11 ladder is suggested (see diagram opposite)."

12 And then if we look at Page 21 -- let's just cull up
13 this diagram that they're referencing.

14 Are you familiar with this diagram?

15 **A.** Yes, I am.

16 **Q.** Have you heard it sometimes referred to as a pain
17 ladder?

18 **A.** Yes, that's what we commonly refer to it as, the World
19 Health Organization pain ladder.

20 **Q.** Can you just walk us through -- I see one, two, three
21 and then references to different types of pain and
22 treatments. Can you walk us through what this pain ladder
23 is communicating?

24 **A.** So it's communicating to doctors and other clinicians
25 that when you encounter a patient with cancer pain, you

1 start with a non-opioid and associated adjuvant medication.
2 If that gives the patient relief, you are typically going to
3 stop there. If it doesn't, you go up to the next level, the
4 next rung.

5 And if pain is persisting or increasing, at that point
6 it's recommending that you start a weak opioid plus those
7 non-opioids plus those adjuvant medications. Again, if that
8 works, you're typically going to stop there.

9 But that if the pain persists or increases, you will
10 then go up another rung. And now you'll go to strong
11 opioids, as well as those non-opioid medications and
12 adjuvants.

13 And you can see at the top that your goal is to achieve
14 for that patient freedom from cancer pain.

15 **Q.** And picking up on that goal, freedom from cancer pain,
16 did there come a time where the concepts reflecting this
17 ladder, stepping up based on the pain and what worked and
18 didn't work, were applied more broadly in the medical
19 profession in cancer pain?

20 **A.** Yes. Over time the same -- this had an influence, of
21 course, on cancer pain. But also it started to have an
22 influence on treatment of pain including non-cancer pain.

23 **Q.** Okay. Let's go back to the timeline, if we could, and
24 again recognizing this is horribly not to scale. But in
25 1995 you put Oxycontin on there.

1 Are you familiar with the FDA's approval of Oxycontin
2 in 1995?

3 **A.** Yes, I am.

4 **Q.** Do you have an understanding as a clinician why it was
5 approved?

6 **A.** My understanding it that it was approved in line with
7 the same approach of trying to have more, more therapies
8 available, more long-acting opioids available to use to
9 treat cancer pain and non-cancer pain to give clinicians
10 more ways to treat pain.

11 **Q.** Do you have an understanding as to whether during that
12 broad time period we're talking about, '80s, '90s, as the
13 medical profession was talking about pain more and opioid
14 analgesics more, the FDA approved several opioids during
15 that time interval?

16 **A.** That is correct.

17 **Q.** Do you know of any role that distributors play in the
18 approval of prescription opioids?

19 **A.** I'm not aware of any role that distributors play in the
20 approval of opioids.

21 MR. FARRELL: Judge, if I may, since we're using a
22 demonstrative, I don't believe the question has been asked
23 to establish the date or the distinction between approved
24 and launched or sold.

25 BY MR. SCHMIDT:

1 Q. Do you know when Oxycontin was approved?

2 A. It was approved in 1995.

3 THE COURT: Does that take care of your objection,
4 Mr. Farrell?

5 MR. FARRELL: Sort of. I also wanted to -- I'll
6 clean it up on cross.

7 THE COURT: Okay. I'll overrule the objection. I
8 think, yeah, it's a matter for cross.

9 Go ahead, Mr. Schmidt.

10 BY MR. SCHMIDT:

11 Q. Okay. I want to ask you about state medical
12 boards. Are you familiar with state medical boards?

13 A. Yes, I am.

14 Q. Do they play a role in, when we talk about standard of
15 care, in setting the standard of care?

16 A. They do.

17 Q. What role do they play?

18 A. So for a doctor to practice, you need your license from
19 your state medical board. And if you were practicing
20 inappropriately, for example, they would be the folks who
21 could pull your license.

22 So, therefore, as, as a doctor, one tends to pay
23 attention to what the state medical board is calling for in
24 terms of appropriate practice.

25 Q. Okay. Did there come a time where state medical boards

1 began to take steps to support broader opioid prescribing?

2 **A.** Yes, there did.

3 **Q.** As part of your work in this case -- and we've got an
4 expert coming next week who's going to dive into this more,
5 so I'm just going to touch this at a very high level.

6 But as part of your work in this case, did you track
7 whether some of these changes in the standard of care
8 tracked into guidance documents from the West Virginia Board
9 of Medicine?

10 **A.** Yes, I did.

11 MR. FARRELL: Judge, I'm going to place an
12 objection on the record. As indicated in my *voir dire*, this
13 witness is certainly an expert in the national standard of
14 care, but is not licensed in West Virginia, does not
15 practice in West Virginia, and has no basis in fact to make
16 any comments about the West Virginia Board of Medicine.

17 MR. SCHMIDT: And, Your Honor, I think the fact
18 that he has general pain management experience, general
19 opioid experience makes him eminently qualified to look at
20 West Virginia Board of Medicine documents and comment on
21 whether they're consistent with --

22 THE COURT: I agree. I think his expertise has
23 been established to the point where I think he's qualified
24 to look at the West Virginia materials and pass an opinion
25 on -- based on those. Overruled.

1 MR. SCHMIDT: And I will be brief with this. May
2 I approach, Your Honor?

3 THE COURT: Yes.

4 MR. SCHMIDT: Thank you, Your Honor.

5 BY MR. SCHMIDT:

6 **Q.** So just to orient us to what we're looking at,
7 we've put it up on the screen, MC-WV-01219 which is in
8 evidence. It's from the State of West Virginia, West
9 Virginia Board of Medicine. And if we look at the
10 second page at the end, we see it was adopted by the
11 West Virginia Board of Medicine in 1997. Do you see
12 that, Dr. Gilligan?

13 **A.** Yes, I do.

14 MR. ACKERMAN: Your Honor, I just want to note
15 that the document, while in evidence, was admitted for a
16 limited purpose, make that clear.

17 MR. SCHMIDT: I don't recall if that's correct or
18 not. But if that's true, we don't take issue with that. I
19 didn't have that recollection, but I'm not -- I didn't look
20 at that.

21 BY MR. SCHMIDT:

22 **Q.** So let's go to the second paragraph of this. It
23 says, "The purpose of this statement is to clarify the
24 Board of Medicine's position on the appropriate use of
25 opioids for patients with chronic non-malignant pain."

1 Let me pause there. What is chronic non-malignant
2 pain?

3 **A.** So chronic non-malignant pain is chronic non-cancer
4 pain.

5 **Q.** Okay. "Clarifying those standards show that these
6 patients will receive quality pain management and so that
7 their physicians will not fear legal consequences, including
8 disciplinary action by the board, when they prescribe
9 opioids in a manner described in this document. It should
10 be understood that the board recognizes that opioids are
11 appropriate treatment for chronic non-malignant pain in
12 selected patients."

13 Do you see that?

14 **A.** I do.

15 **Q.** Is this consistent with this change in national
16 standards that you've been telling us about at this time in
17 the 1997 time period?

18 **A.** Yes, it is.

19 **Q.** All right. Let's go two lines -- two paragraphs down.
20 You talked about the role that state medical boards play in
21 discipline. Do you remember telling us about that just a
22 moment ago?

23 **A.** I do.

24 **Q.** It says, "A physician need not fear disciplinary action
25 by the board if complete documentation of prescribing of

1 opioids in chronic non-malignant non-cancer pain even in
2 large doses is contained in the medical records."

3 Do you see that?

4 **A.** I do.

5 **Q.** And if we can go back to the timeline and put that
6 quote on the timeline under 1997.

7 Just in general terms, what's the import of a statement
8 like that from a, from a State Board of Medicine?

9 **A.** So for a doctor, that's a clear message. It's very
10 clearly written saying that if you prescribe opioids even in
11 large doses for non-cancer pain -- and there is a reference
12 that you're going to have to have complete documentation.
13 You're going to have to justify your decision to do that in
14 your medical record which would be for a doctor expected.
15 That in that case, you need not fear disciplinary action.

16 And that's -- that would typically be quite significant
17 to a physician because disciplinary action from a medical
18 board could mean losing your medical license and not being
19 able to practice medicine, for example.

20 **Q.** Are you familiar with something called the Federation
21 of State Medical Boards?

22 **A.** Yes, I am.

23 **Q.** Could you tell us what the Federation of State Medical
24 Boards is?

25 **A.** So it's a group that tends to write guidelines and

1 documents for -- that are then frequently adopted by medical
2 boards in the different states.

3 **Q.** Okay. Are you familiar with publications that the
4 Federation of State Medical Boards has issued over time
5 regarding prescription opioids?

6 **A.** Yes, I am.

7 MR. SCHMIDT: May I approach, Your Honor?

8 THE COURT: Yes.

9 BY MR. SCHMIDT:

10 **Q.** I've given you what I've marked as Defense West
11 Virginia 2937. If you look at the top of it -- well,
12 actually, let's look at the second line -- the third
13 line, smaller print.

14 Do you see in that sentence there's a reference to the
15 Federation of State Medical Boards, and it's dated May,
16 1998. Do you see that?

17 **A.** I do.

18 **Q.** And it says, "Model guidelines for the use of
19 controlled substances for the treatment of pain."

20 Are you familiar with this document?

21 **A.** Yes, I am.

22 **Q.** At a high level, can you give us an overview of, of
23 what this document is?

24 **A.** So it's a document written by the Federation of State
25 Medical Boards spelling out their, their guidelines for the

1 appropriate use of controlled substances to treat pain.

2 And then this is the, the -- this sort of document --
3 indeed, this one was -- the sort of document that many state
4 medical boards would then adopt as their, as their
5 guideline.

6 MR. SCHMIDT: Your Honor, we missed the ancient
7 records exception by a few months for this document, so I'll
8 take up Mr. Farrell's invitation to move it in just for the
9 limited purpose of notice, Defense West Virginia 2937.

10 THE COURT: Is there any objection?

11 MR. FARRELL: No, Your Honor.

12 THE COURT: It's admitted for the limited purpose.

13 BY MR. SCHMIDT:

14 **Q.** Let's look at some of the language in this
15 document.

16 First of all, if you go to the third paragraph, please,
17 it states, "The board recognizes that controlled substances,
18 including opioid analgesics, may be essential in the
19 treatment of acute pain due to trauma or surgery and chronic
20 pain whether due to cancer or non-cancer origins."

21 Are you familiar with that statement from the
22 Federation of State Medical Boards in 1998?

23 **A.** Yes, I am.

24 **Q.** And if we go over to the timeline and put that on a
25 timeline, 1998, can you comment on the significance, if any,

1 of the Federation of State Medical Boards issuing this
2 broader statement including the specific recognition that
3 opioid analgesics may be essential for acute pain due to
4 trauma or surgery and chronic pain whether due to cancer or
5 non-cancer?

6 **A.** So it's part of the same change over time and
7 encouraging increase in the -- essentially increase in the
8 aggressive treatment of pain with the, the, this concept
9 that we've been perhaps under-treating pain.

10 And it's significant that they're spelling out not just
11 acute pain and not just chronic pain due to cancer, but also
12 including chronic pain due to non-cancer origins.

13 **Q.** And do you understand this to be consistent with the
14 standard of care regarding prescription opioids as it was
15 developing in this time period?

16 **A.** Yes, I do.

17 **Q.** Let's go back to the article itself, please, Defense
18 West Virginia 2937. And if we go back to that third
19 paragraph, I just want to cull out some other language at
20 the end.

21 "Physicians should recognize that tolerance and
22 physical dependence are normal consequences of sustained use
23 of opioid analgesics and are not synonymous with addiction."

24 Can you explain to us what you understand the
25 Federation of State Medical Boards to be saying with that

1 statement?

2 **A.** So what they're spelling out for physicians is -- and I
3 agree with them, by the way -- if, if you prescribe a
4 significant dose of opioids to any patient over a
5 significant time period, that patient will become physically
6 dependent.

7 So if you were to abruptly stop those opioids from one
8 day to the next, that patient would have a physical
9 withdrawal and would be sick. But that's not being
10 addicted. That's just a physical dependence that happens to
11 everybody. In fact, it happens to every mammal if you give
12 a significant dose over a significant time.

13 Similarly, the tolerance is that if you give a
14 significant dose over a significant time, the medication
15 will have less effect. The patient will become tolerant.
16 And, again, that's a normal physiologic thing that will
17 happen to everybody with a sufficient dose over a sufficient
18 time, whereas addiction is something that's a psychological
19 phenomenon, compulsive use cravings, that does not happen to
20 everybody. It happens to a relatively small percentage of
21 patients. When it does happen, it can be absolutely
22 devastating, so as to not confuse the patient developing
23 physical dependence or physical tolerance with a patient
24 developing addiction.

25 **Q.** And I'd like to go to the next stop on the timeline.

1 Before I do, we've been focusing on some seminal
2 publications relevant to the standard of care question.

3 Do you have an understanding as to whether there was a
4 much broader discussion occurring regarding standard of care
5 that these are leading examples of?

6 **A.** These are examples of the evolution of that standard of
7 care, but they reflect a broad discussion across pain
8 medicine, and actually medicine in general, about what's the
9 appropriate way for us to treat pain and what's the
10 appropriate way for us to use opioid pain medications to
11 treat pain.

12 MR. SCHMIDT: May I approach, Your Honor?

13 THE COURT: Yes.

14 BY MR. SCHMIDT:

15 **Q.** I've passed you a document AM-WV-2693. It says
16 "Joint Commission on Accreditation of Healthcare
17 Organizations Pain Standards for 2001." Are you
18 familiar with this document?

19 **A.** Yes, I am.

20 **Q.** Are you familiar with the entity that issued this
21 document, the Joint Commission on Accreditation of
22 Healthcare Organizations?

23 **A.** Yes, I am. We, we call it by the acronym JCAHO.

24 **Q.** And what role, if any, do they play in the medical
25 profession?

1 **A.** So JCAHO is the body that accredits hospitals and they
2 accredit other healthcare organizations. And that
3 accreditation is very important to us to continue to be able
4 to operate our hospitals. An accredited hospital has
5 implications for reimbursement, et cetera. So their
6 accreditation is extremely important to us.

7 **Q.** And these are, are pain standards for 2001. What, if
8 anything, is the significance of this accreditation on
9 issuing pain standards, or any kind of standards for that
10 matter?

11 **A.** So the significance of any standards that JCAHO issues
12 is that they come and inspect us on a regular basis. Often
13 it's a surprise inspection that you don't know of ahead of
14 time where they arrive. And they inspect whether we're
15 meeting their standards for pain treatment or for keeping
16 the operating rooms sterile, clean enough, or many other
17 things.

18 And it's very, very important to us to maintain our
19 accreditation, and very important for us not to have
20 findings where we're not meeting their standards beyond how
21 we treat pain or other things.

22 **Q.** Okay. In terms of these specific pain standards, do
23 you know whether they are influential in the practice of
24 medicine?

25 **A.** Yes, I do.

1 Q. How so -- or how were they if at all?

2 A. So they were influential because they set standards for
3 measuring pain as the fifth vital sign --

4 Q. Uh-huh.

5 A. -- which was extremely important because if you think
6 of vital signs, the name, the name says a lot; heart rate,
7 blood pressure, et cetera, key things. And to then add pain
8 as a fifth vital sign was a very clear message of how
9 important JCAHO felt measuring pain and, by implication,
10 treating pain was and so, therefore, the expectation that
11 hospitals who are going to be inspected by JCAHO would,
12 would meet those sort of standards.

13 Q. I'd like to look at what exactly this document says on
14 that.

15 MR. SCHMIDT: Before I do, we move this document
16 into evidence for the limited purpose of notice, AM-WV-2693.

17 MR. ACKERMAN: One thing, Your Honor -- we tried
18 to point this out last night in our objections. It appears
19 that the back there's a different document that's appended
20 to it. So you've got ten pages that all appear to be the
21 same document, and then there's something else.

22 THE COURT: Beginning on page --

23 MR. ACKERMAN: Page 11 at the bottom it looks like
24 something that is Page 13 of a separate document.

25 MR. SCHMIDT: I think the cover of the document

1 answers that in the second paragraph. It refers to the new
2 pain standards and some examples are pulled out of the six
3 chapters in which they appear in these six manuals and are
4 shown below for your information.

5 So it's, it's an attachment to the original document
6 that's referenced in the second paragraph on the first page.

7 THE COURT: Yeah. The paragraph on the first page
8 appears to embrace the parts that you're concerned about,
9 does it not?

10 MR. ACKERMAN: I think when it says examples are
11 shown below, it's talking about the content of the document.

12 MR. SCHMIDT: This document has been on the
13 exhibit list for a long, long time. It's one of the central
14 documents in the case. I actually moved it into evidence as
15 an adoptive admission because it's subject to a --

16 THE COURT: I'm going to admit it for the limited
17 purpose, Mr. Ackerman. You can object -- do you want the
18 record to show your objection?

19 MR. ACKERMAN: I think it's on the record, Your
20 Honor.

21 THE COURT: All right. It will do so.

22 BY MR. SCHMIDT:

23 **Q.** Let's go to Page 12 of this document if we could.
24 It's the number in the middle this time at the bottom.
25 And it says "Standard" at the top.

1 And, actually, just before I do, just to make the
2 record complete, Dr. Gilligan, could you look back with me
3 at the first page of the document.

4 The second paragraph says, "The new pain standards and
5 some examples are pulled out of the six chapters in which
6 they appear in these six manuals and are shown below for
7 your information."

8 Do you see that?

9 **A.** I do.

10 **Q.** Let's go to Page 11. Remembering those, those words
11 from the first page about standards and manuals -- I'm
12 sorry, Page 12, please.

13 You see at the top there's a reference to a manual, the
14 Comprehensive Accreditation Manual for Hospitals: The
15 Official Handbook. Do you see that?

16 **A.** I do.

17 **Q.** And then below that there's a reference to "Standard."
18 Do you see that?

19 **A.** I do.

20 **Q.** The standard is patients have the right to appropriate
21 assessment and management of pain. Do you see that?

22 **A.** I do.

23 **Q.** And then it looks like the way this document works is
24 it explains that standard. And it says, "Pain can be a
25 common part of the patient experience. Unrelieved pain has

1 adverse physical and psychological effects. The patient's
2 right to pain management is respected and supported. The
3 healthcare organization plans, supports, and coordinates
4 activities and resources to assure the pain of all patients
5 is recognized and addressed appropriately."

6 Do you see that?

7 **A.** I do.

8 **Q.** And what, if anything, is the import of this being part
9 of an accreditation manual and standard set of that manual
10 in JCAHO?

11 **A.** So it's of substantial import again because we are
12 accredited by JCAHO and because it's very, very important to
13 us to maintain our accreditation, and very important for our
14 accreditation inspections not to have findings where we're
15 deficient. So in a set of standards like this, that has a
16 big effect on, on us running the hospital.

17 **Q.** Let's go back to the page we were looking at, please,
18 if you could pull that back up, 2693, AM-WV-2693, Page 12.

19 And while we're pulling that up, we can look at our
20 hard copy documents just in the interest of time.

21 Do you see there's a heading below the standard below
22 the explanation of the intent of the standard that says
23 "examples of implementation"? Do you see that?

24 **A.** I do.

25 **Q.** And do you see the references, what you were telling us

1 earlier, it says, "Pain is considered a fifth vital sign in
2 the hospital's care of patients. Pain intensity ratings are
3 recorded during the admission assessment along with
4 temperature, pulse, respiration and blood pressure."

5 Do you see that?

6 **A.** I do.

7 **Q.** And was that a significant consideration in the
8 standard of care in medicine at this time?

9 **A.** That was a significant consideration again because the,
10 the other vital signs have been around for -- temperature,
11 pulse, respiration, blood pressure have been vital signs
12 that are critical to assessing patients.

13 And, so, to add pain as a fifth vital sign was a very
14 clear message about the great importance of measuring pain
15 and, by implication, of treating pain.

16 **Q.** Okay. And you see that as, as Item Number 1 under
17 examples. And let's just go to the board and put that up on
18 the board.

19 We're now to 2001. Pain is considered the fifth vital
20 sign.

21 Can we go back to the second example, AM-WV-2693.
22 "Every patient is asked a screening question regarding pain
23 on admission."

24 And then let's just jump down to Number 4. "The
25 following statement on pain management is posted in all

1 patient care areas (patient rooms, clinic rooms, waiting
2 rooms, et cetera). Statement on pain management: All
3 patients have a right to pain relief."

4 Could you comment on the impact of some of these
5 examples that were given on how to implement this policy in
6 terms of every patient being asked a screening question
7 about pain, public postings that we've probably all seen,
8 all patients have a right to pain relief.

9 **A.** So where every patient is asked a screening question
10 about pain on admission, then you're getting a measurement
11 of pain by JCAHO guidance on every patient. And that's
12 extremely likely to have an effect that you'll now be doing
13 more to treat patients' pain.

14 If the measurement is very high, the likelihood that
15 doctors and nurses will then do something to try to treat it
16 is, I think, a borne out conclusion. And also having the
17 statement posted in all patient care areas per JCAHO
18 recommendations, per JCAHO standard setting saying all
19 patients have a right to pain relief is, is a very clear
20 statement that if a patient has severe pain, there's a
21 strong implication that doctors and nurses should, in the
22 appropriate fashion one would hope, treat, treat their pain.

23 **Q.** Let's go to the next item on the timeline.

24 MR. SCHMIDT: May I approach, Your Honor?

25 THE COURT: Yes.

1 BY MR. SCHMIDT:

2 Q. I've given you MC-WV-1522 which is titled "A Joint
3 Statement from 21 Health Organizations and the Drug
4 Enforcement Administration."

5 And then if you look on the right, it appears that it
6 lists the different organizations. Do you see that?

7 A. I do.

8 Q. And one of them is -- the sixth one down is the
9 American Medical Association. Do you see that?

10 A. I do.

11 Q. What is the import, if anything, of receiving a
12 statement from the American Medical Association?

13 A. The American Medical Association is the biggest
14 organization representing doctors in America. So it's
15 significant when they're endorsing a statement.

16 Q. If you scroll down, this was in the title, but do you
17 see the reference to the Drug Enforcement Administration
18 being listed?

19 A. I do.

20 Q. And it's on the right there, yeah. And then if we go
21 back to what this joint statement addresses, it states,
22 "Promoting pain relief and preventing abuse of pain
23 medications, a critical balancing act."

24 Do you see that?

25 A. I do.

1 **Q.** Is there -- what significance, if any, does a statement
2 from the DEA on balancing pain relief and preventing abuse
3 to pain medications carry?

4 **A.** So it's significant because the Drug Enforcement
5 Agency, of course, part of what they're, what they will do
6 is look at inappropriate use of medications and be an
7 enforcement agency.

8 So when they're endorsing promoting pain relief while
9 getting the -- while preventing abuse, that's significant
10 because the doctor who would be -- might be scared to
11 prescribe opioids for fear of getting in trouble with
12 enforcement agencies would take -- would tend to take quite
13 seriously a message from the Drug Enforcement Agency
14 endorsing these medications to treat pain in many
15 situations.

16 MR. SCHMIDT: I'll move into evidence MC-WV-1522
17 for the limited purpose of notice.

18 THE COURT: Any objection?

19 MR. ACKERMAN: For the limited purpose, no
20 objection.

21 THE COURT: Let me make clear it's notice to, to
22 whom for what?

23 MR. SCHMIDT: Notice to the medical and healthcare
24 community regarding the contents --

25 THE COURT: Regarding the changing standards of

1 the abuse of opioids?

2 MR. SCHMIDT: Yes, Your Honor.

3 MR. FARRELL: I've got an objection to that. I
4 think it's notice to the defendants, not notice to --
5 there's no relevance to the notice to the community.

6 MR. SCHMIDT: It's a publication from, among other
7 sources, the American Medical Association and the branch of
8 the federal government that regulates all doctors who
9 prescribe prescription opioids. We're talking about
10 standard of care. I think it is relevant to notice to
11 doctors.

12 THE COURT: I think it is too, Mr. Farrell. It
13 shows the -- it doesn't come in for the truth of the matter
14 asserted. It comes in to show notice to the medical
15 profession of the changing standards of the use of opioids.
16 Isn't that the purpose it's offered, Mr. Schmidt?

17 MR. SCHMIDT: Yes. I think we actually could move
18 it in as a public record.

19 MR. FARRELL: Okay.

20 THE COURT: I'll admit it for the limited purpose.

21 Do you want to object, Mr. Farrell?

22 MR. FARRELL: No. I guess I'm just a little
23 confused, but that's okay.

24 BY MR. SCHMIDT:

25 Q. So let's look at what this statement says. If we

1 look -- there's a line, looks like the third paragraph
2 down, "This consensus statement is necessary based on
3 the following facts." And then it lists a series of
4 facts. I'm going to focus on the first two. Do you see
5 that?

6 **A.** I do.

7 **Q.** The first fact, according to this document, that
8 necessitates this consensus statement is that, quote,
9 "Under-treatment of pain is a serious problem in the United
10 States, including pain among patients with chronic
11 conditions and those who are critically ill or near death.
12 Effective pain management is an integral and important part
13 of the quality of medical care and pain should be treated
14 aggressively."

15 Do you see that language?

16 **A.** Yes, I do.

17 **Q.** Again, does this reflect the standard of care this time
18 from the entire American Medical Association and the DEA
19 about the needs, in the words of this document, to not
20 simply recognize the problem with under-treatment of pain,
21 but that pain should be treated aggressively?

22 **A.** Yes, this is part of that changing standard of care.

23 **Q.** Let's look at the next bullet. It says, "For many
24 patients opioid analgesics, when used as recommended by
25 established pain management guidelines --" do you see that

1 language?

2 **A.** I do.

3 **Q.** And what do you understand that reference to mean,
4 established pain management guidelines?

5 **A.** Things like the guidance from the Federation of State
6 Medical Boards and other similar guidelines.

7 **Q.** "For many patients, opioid analgesics, when used as
8 recommended, are the most effective way to treat their pain
9 and often the only treatment option that provides
10 significant relief." And did I read that correctly?

11 **A.** Yes, you did.

12 **Q.** If we switch over to our board and put that on the
13 board, is that significant when the DEA and the AMA are
14 coming out with a statement saying that it's important to
15 treat pain and they're often the only treatment option that
16 provides significant relief?

17 **A.** Yes, it's important, again the AMA being the biggest
18 organization representing doctors in the U.S. and the DEA
19 being the Drug Enforcement Agency.

20 **Q.** Okay. Can we go back to the original document, please,
21 MC-WV-1522. And do you still have that in front of you?

22 I think we're having some technical problems. While
23 we're doing that, I'm going to ask you about one other
24 paragraph in here. It's the third paragraph in the document
25 right before that discussion of the consensus statement

1 being necessary based on the following facts.

2 Do you see where it says, "Preventing drug abuse is an
3 important societal goal but there's consensus by law
4 enforcement agencies, healthcare practitioners, and patient
5 advocates alike that that concern should not hinder a
6 patient's ability to receive the care they need and
7 deserve."

8 Do you see that language?

9 **A.** I do.

10 **Q.** Do you have an understanding that there was that
11 consensus described here at this point in time by law
12 enforcement, by healthcare practitioners, by patient
13 advocates that concerns about abuse were important, but they
14 shouldn't hinder a patient's ability to receive the care
15 they need?

16 **A.** Yes. My understanding is that that was the consensus
17 view at that time.

18 **Q.** The FSMB continued to issue guidelines over time?

19 **A.** Yes, they did.

20 **Q.** Let's take a look at the next set of guidelines, if I
21 may just have one second, Your Honor.

22 THE COURT: Yes.

23 MR. SCHMIDT: May I approach?

24 THE COURT: Yes.

25 BY MR. SCHMIDT:

1 **Q.** I've handed you what I've marked as Defense West
2 Virginia 3605. And let's put it up on the screen just
3 in terms of what we're looking at. It says "Model
4 Policy for the Use of Controlled Substances, Federation
5 of State Medical Boards." And then there's a reference
6 to May, 2004. Do you see that?

7 **A.** I do.

8 **Q.** Is this an update on those Federation of State Medical
9 Board standards now from 2004?

10 **A.** That's correct.

11 MR. SCHMIDT: We'd move this into evidence for the
12 limited purpose of notice as described before, Your Honor.

13 THE COURT: Any objection?

14 (No Response)

15 THE COURT: Hearing none, it's admitted.

16 BY MR. SCHMIDT:

17 **Q.** If we look in the second paragraph, it states,
18 "Since adoption in April 1998 --"

19 Is that a reference to the earlier guidelines we looked
20 at?

21 **A.** Yes, it is.

22 **Q.** "-- the model guidelines for the use of controlled
23 substances for the treatment of pain have been widely
24 distributed to state medical boards, medical professional
25 organizations, other healthcare regulatory boards, patient

1 advocacy groups, pharmaceutical companies, state and federal
2 regulatory agencies, and practicing physicians and other
3 healthcare providers. The model guidelines have been
4 endorsed by the American Academy of Pain Medicine, the Drug
5 Enforcement Administration, the American Pain Society, and
6 the National Association of State Controlled Substances
7 Authorities."

8 Do you have that understanding that their model
9 guidelines were endorsed by various organizations, including
10 the DEA?

11 **A.** Yes, that is my understanding.

12 **Q.** Let's go to the next paragraph, please.

13 It states, "Notwithstanding progress to date in
14 establishing state pain policies recognizing the legitimate
15 uses of opioid analgesics, there is a significant body of
16 evidence suggesting that both acute and chronic pain
17 continue to be under-treated."

18 Do you see that?

19 **A.** I do.

20 **Q.** So just to orient us, we're now in 2004. Are you aware
21 that prescription levels had actually started increasing by
22 this point in time?

23 **A.** Yes, I am aware they had.

24 **Q.** Was the Federation of State Medical Boards telling
25 doctors they could still do more to treat acute and chronic

1 pain?

2 **A.** Yes, I think that's a fair statement of what they're,
3 of what they're saying.

4 **Q.** Let's go to Page 3. Actually, let's just put that
5 statement, if we could, up on the board.

6 We're now to 2004. Recognizing that they continued --
7 let's go back to Defense West Virginia 3605 at the bottom of
8 Page 2, last sentence, or second to last sentence.

9 It says, "Appropriate pain management is the treating
10 physician's responsibility. As such, the board will
11 consider the inappropriate treatment of pain to be a
12 departure from standards of practice and will investigate
13 such allegations, recognizing that some types of pain cannot
14 be completely relieved, and taking into account whether the
15 treatment is appropriate for the diagnosis."

16 What's the import of the Federation of State Medical
17 Boards proposing that the medical standard will involve the
18 board considering inappropriate treatment of pain to be a
19 departure from standards of practice and will investigate?

20 **A.** So what the Federation of State Medical Boards is
21 telling doctors there is that if you do not adequately treat
22 patients' pain, you will have failed to meet the standards
23 of care, or standard of practice care they use.

24 And, again, where medical boards are the bodies that
25 grant you your license and can take your license away, a

1 recommendation of that sort from the Federation of State
2 Medical Boards has a significant influence on doctors.

3 **Q.** Next sentence repeats or says something similar.

4 Can you cull that out, the next sentence on Page 3?

5 "The board recognizes that controlled substances,
6 including opioid analgesics, may be essential in the
7 treatment of acute pain due to trauma or surgery and chronic
8 pain, whether due to cancer or non-cancer origins."

9 Is that a similar statement about the role of
10 prescription opioids that we saw in the earlier document?

11 **A.** Yes, it's very similar. And, again, it specifically
12 calls out chronic non-cancer origin in addition to acute
13 pain and cancer pain.

14 **Q.** Okay. Let's go to the next document on our timeline.
15 I want to just illustrate whether this tracked through into
16 West Virginia standards with a document in evidence.

17 MR. SCHMIDT: May I approach, Your Honor?

18 THE COURT: Yes. I don't think you moved 3065
19 into evidence. Do you want to do that?

20 MR. SCHMIDT: Yes, I would for the limited purpose
21 of notice, Your Honor.

22 THE COURT: All right. Is there any objection?

23 MR. ACKERMAN: Not for the limited purpose.

24 THE COURT: All right. It's admitted for the
25 limited purpose.

1 MR. SCHMIDT: Thank you, Your Honor.

2 BY MR. SCHMIDT:

3 Q. So if we put MC-WV-1218 up on the screen, do you
4 see that this is a West Virginia Board of Medicine
5 quarterly newsletter from January, 2005?

6 A. I do.

7 Q. And just two quick points on this.

8 If we can scroll down, please, to the first paragraph.

9 Remember in that earlier document there was a reference
10 to the inappropriate treatment of pain?

11 A. I do.

12 Q. Do you see that defined here in this last sentence for
13 the purposes of this policy, the inappropriate treatment of
14 pain includes non-treatment, under-treatment,
15 over-treatment, and the continued use of ineffective
16 treatments?

17 A. I, I see that.

18 Q. And then I just want to look down at the bottom of this
19 page. Do you remember me reading you that language from the
20 FSMB document about the board will consider the
21 inappropriate treatment of pain to be a departure from
22 standards?

23 A. I do.

24 Q. Do you see that same language here adopted by the State
25 of West Virginia, "The board will consider the inappropriate

1 treatment of pain to be a departure from standards of
2 practice and will investigate such allegations."

3 Is that guided by the Federation of State Medical
4 Boards?

5 **A.** That would be my understanding because it's verbatim
6 from what we saw in the FSMB.

7 **Q.** And if we go to the next page, please, do you see a
8 similar statement from the West Virginia Board of Medicine
9 right at the top recognizing that opioids may be essential
10 in the treatment of acute pain due to trauma or surgery and
11 chronic pain whether due to cancer or non-cancer?

12 **A.** I see that.

13 **Q.** And let's, let's put that up on the board if we could.

14 The Court has heard evidence about a book by a Dr.
15 Fishman and I'm not going to -- it's in evidence. The Court
16 has a copy. I'm not going to spend a lot of time on it. It
17 was actually mailed to every doctor in West Virginia called
18 "Responsible Opioid Prescribing." Are you familiar with
19 that Dr. Fishman book?

20 **A.** Yes, I'm familiar with the book.

21 **Q.** And if we -- let's put up on the screen MC-WV-2111 and
22 go to Page 15 of the document.

23 I want to just highlight some language the Court has
24 seen.

25 "Patients should not be denied opioid medications

1 except in light of clear evidence that such medications are
2 harmful to the patient."

3 Do you see that?

4 **A.** I do.

5 MR. SCHMIDT: Mr. Reynolds, can you put that up on
6 our board?

7 BY MR. SCHMIDT:

8 **Q.** We're now to 2008 and the corresponding
9 transmission of this to all doctors in West Virginia.

10 MR. SCHMIDT: And if we go back to the book itself
11 and cull out that first bullet that was on Page 15. Then
12 can you also cull out the third bullet. Is it possible to
13 get both of them together?

14 BY MR. SCHMIDT:

15 **Q.** I read you the first one. The third one says,
16 "Physicians have a responsibility to minimize the
17 potential for the abuse and diversion of controlled
18 substances."

19 Do you see that?

20 **A.** I do.

21 **Q.** Do you understand this book that was sent to every West
22 Virginia doctor to be in line with standard of care at this
23 time in terms of when opioids should be prescribed and
24 having a responsibility to minimize the potential for abuse
25 and diversion?

1 **A.** Yes. I think it was a clear message that on the one
2 hand doctors should appropriately use opioids to treat
3 patients' pain, but that also doctors have a responsibility
4 to think beyond just the patient in front of them to think
5 about the potential for abuse and diversion of those
6 medications.

7 **Q.** Okay. How do you mesh those two statements?

8 **A.** I mesh those two in terms of the same sort of balancing
9 that I think is characteristic in many areas of the practice
10 of medicine, and certainly in this area of prescribing
11 opioid medications that you're talking about, you're talking
12 about significant potential benefits, but you're also
13 talking about significant potential risks, and that the
14 doctor is -- as part of his or her job is supposed to think
15 through those, that risk benefit and weigh it as
16 appropriately as he or she can with the information
17 available to them.

18 **Q.** Two more documents on this timeline if I could.

19 MR. SCHMIDT: May I approach, Your Honor?

20 THE COURT: Yes.

21 BY MR. SCHMIDT:

22 **Q.** And I'll try to do these as quickly as possible.

23 The first document is Defense West Virginia 1944 which
24 is not in evidence. The second document is Defense West
25 Virginia 1935 which is in evidence.

1 My question to you is simply if you -- Defense West
2 Virginia 1944 is dated --

3 MR. ACKERMAN: Your Honor, --

4 MR. SCHMIDT: -- 2005.

5 MR. ACKERMAN: We have an objection to the use of
6 Defense West Virginia 1944 because the document did not
7 appear on the expert's materials considered list.

8 MR. SCHMIDT: It does not. That is correct. It's
9 substantively identical in terms of what I'm asking him
10 about to the later version of the document that does.

11 MR. ACKERMAN: Your Honor, I think we went through
12 this with some of our experts that materials that weren't in
13 the report you're not allowed to ask about.

14 THE COURT: Well, I'll sustain the objection. You
15 can use it as a basis to ask him a question if you want to,
16 Mr. Schmidt.

17 BY MR. SCHMIDT:

18 **Q.** Okay. Let's start with Defense West Virginia 1935,
19 Page 2. Do you recognize this is from September 9th,
20 2013, from the State of West Virginia policy on the use
21 of opioid analgesics?

22 **A.** I do.

23 **Q.** If you look a little further up, do you see that in
24 this one they're actually clear that they took it from these
25 Federation of State Medical Board documents we've been

1 talking about?

2 **A.** I see that.

3 **Q.** And in the interest of time, I will go to the third
4 page of this document. And do you see in the third
5 paragraph, the first sentence references again the statement
6 about opioid analgesics are useful and can be essential in
7 the various range of pain treatments that we've talked
8 about, acute pain, chronic pain, whether due to cancer or
9 non-cancer causes?

10 **A.** I see that.

11 **Q.** And if we go to the two paragraphs down, patients
12 (verbatim) should not fear disciplinary action from the
13 board for ordering, prescribing, dispensing or administering
14 controlled substances, including opioid analgesics, for a
15 legitimate medical purpose in the course of professional
16 practice when current best clinical practices are met.

17 Do you see that?

18 **A.** I do.

19 **Q.** And then if we look at the next sentence, they define
20 when use of opioids is for a legitimate medical purpose.
21 And they say if it's based on sound clinical judgment and
22 current best clinical practices, is appropriately documented
23 and is of demonstrable benefit to the patient. Do you see
24 that?

25 **A.** I do.

1 **Q.** What's the import of a State Board of Medicine telling
2 doctors in that state, statements like this about
3 appropriate use of, of prescription opioids?

4 **A.** The importance of it is that the State Medical Board is
5 giving physicians here a fairly clear message that they
6 would not be -- they shouldn't fear disciplinary action by
7 the board as long as they practice meeting the standards of
8 appropriate care. And, so, that they shouldn't let that
9 fear of potential discipline stop them from using opioid
10 pain medications in an appropriate fashion.

11 **Q.** Do you see similar statements -- let's go to the board.
12 Let's put up the two documents we just used, Defense West
13 Virginia 1944 from 2010 and Defense West Virginia 1935 from
14 2013 on the board. Do you see similar statements in between
15 2005 and 2013?

16 **A.** I did.

17 **Q.** Okay.

18 MR. SCHMIDT: Your Honor, may I pass up a copy of
19 this for demonstrative purposes? Plaintiffs' counsel
20 already has it.

21 THE COURT: Yes.

22 MR. ACKERMAN: Of what?

23 MR. SCHMIDT: Of the completed time line.

24 MR. ACKERMAN: Oh, okay.

25 MR. SCHMIDT: Thank you.

1 Your Honor, I briefly conferred with Mr. Farrell. I
2 have about 10 minutes left. I was hoping to be done. Mr.
3 Farrell was very gracious to say if I'm not done by noon
4 that that gives him enough time. This might be -- if that's
5 okay with the Court, this might be a good time to break.

6 THE COURT: Yeah, let's go ahead and finish the
7 direct and then we'll take the lunch break and come back and
8 you can cross him after lunch.

9 MR. FARRELL: I think Mr. Schmidt was asking
10 whether or not he could take 10 minutes after the break to
11 finish up and that way --

12 THE COURT: Is that what you were asking?

13 MR. SCHMIDT: Yes, but I'm good either way, Your
14 Honor.

15 THE COURT: Well, I'm going to suggest we come
16 back at 1:30. Is that okay with everybody?

17 MS. MAINIGI: Yes, Your Honor.

18 THE COURT: We'll be in recess until then.

19 (Recess taken at 12:01 p.m.)

20 (Proceedings resumed at 1:27 p.m. as follows:)

21 THE COURT: Okay, Mr. Majestro.

22 MR. MAJESTRO: Your Honor, you asked me yesterday
23 how much time we needed to respond to the motions and I
24 wisely waited to see them before I committed myself.

25 Following court yesterday, the defendants began filing

1 motions, ended over the noon hour. They filed five motions
2 totaling 214 pages of text, none of them within the Court's
3 page limits.

4 I understand these are important issues, but I would
5 point out two things about the issues.

6 A lot of what's here is either, is either an attempt to
7 re-litigate issues in a -- with different theories or
8 arguments that have never been raised before in this
9 litigation.

10 Mr. Heard yesterday talked about, "After four years I
11 still haven't seen a case," or such and such. Well, this
12 is -- the first time he raised that argument was yesterday.

13 And, so, we've had U.S. Supreme Court precedent going
14 back to historical roots of equity jurisdiction. It's
15 complicated.

16 In addition, you know, our team -- we're allocating
17 resources among the lawyers working on these cases across
18 the country. Our teams have split up. We have people
19 currently working on the, on the State Court cases in
20 California, in New York, and also getting ready for the --
21 Judge Polster's trial. They're getting ready to -- getting
22 the dispositive motions and *Daubert* deadlines for those
23 trials.

24 And as I mentioned to your law clerk before the
25 hearing, I also have a personal event next week that's going

1 to have me out-of-pocket for a few days.

2 With all that, we're not going to file a motion to
3 strike these motions for violation of the page limits. And
4 I, I admit that we have been a little lax in those. But
5 it's always been done by consent and never to the extent
6 that this has happened.

7 But you asked me how much time I needed to do the right
8 kind of job and it's a month.

9 THE COURT: Ms. Mainigi.

10 MS. MAINIGI: Your Honor, I think a month is, is
11 just way too long for these motions. I mean, they're
12 clearly timely motions and we know that we filed a lot of
13 papers. I think our papers are exactly on point and
14 consistent with what we needed to file for directed verdict
15 motions.

16 And, so, with respect to -- there's a couple of points.

17 Number one, they have seven law firms that are working
18 on this matter. So there are -- I certainly don't begrudge
19 Mr. Majestro taking time off for his daughter's wedding.
20 Absolutely he should be doing that. But I think that
21 there -- just like we've had to divide up our resources
22 across the country in various jurisdictions, they have done
23 the same thing and this is a trial. We're in the midst of
24 trial and we're moving.

25 THE COURT: Have the defendants filed everything

1 they intend to file with regard to the 52(c) motions?

2 MS. MAINIGI: Yes, Your Honor, to my knowledge.

3 I'm not aware of --

4 THE COURT: So you're done?

5 MS. MAINIGI: We're, we're done, Your Honor.

6 And one key important fact that I'd like to share with
7 the Court, which I hope will make everybody's Friday
8 afternoon, we've been taking a close look at our case and
9 we've been taking a look at the types of, the pieces of
10 evidence that we were able to get in during discovery,
11 especially since many of our corporate witnesses were called
12 in the plaintiffs' case. And, and we think that we're
13 looking on the outside at three more weeks of trial.

14 So, obviously, some of that is dependent on how long
15 the cross-examinations will be. And, certainly, I don't
16 want to delay Dr. Gilligan by slowing this down on the
17 schedule. We're certainly happy to discuss that with you
18 all whenever you're ready. But when we're looking at on the
19 outside three weeks of trial, I do think a month ultimately
20 for briefing and directed verdict is just not feasible.

21 And so our suggestion, Your Honor, is that the
22 proximate cause motion, for example, could be filed within a
23 week, and then everything else within two weeks. And I do
24 think that the plaintiffs have the resources to get that
25 done.

1 There is many a time where we have made filings
2 overnight and utilized all of our resources, even those
3 folks not in trial, to get that work done at the end of the
4 day.

5 So we think that would be quite reasonable under the
6 circumstances, one week for proximate cause and then two
7 weeks for the balance given that we're looking on the
8 outside at three weeks.

9 THE COURT: Mr. Majestro, how much time do you
10 need to take off for your daughter's wedding? I want you to
11 go and have a good time.

12 MR. MAJESTRO: I, I was planning on being gone
13 Thursday, Friday. I'm putting on one witness next week
14 also.

15 The other point I'd make, Your Honor, is that the --
16 then I planned to be not working the entire weekend.

17 You know, Rule 52(c) -- this sounds to me like if these
18 issues are that complicated that they needed to file two
19 hundred and some pages of briefs that maybe this is another
20 ground for exercising your jurisdiction and deferring ruling
21 on these.

22 If they're going to be done in three weeks, that, that
23 seems to me -- I mean, I -- even under their schedule I
24 assume they're going to be filing a reply. And, so, it
25 seems to me we're going to be at the end of trial anyway.

1 And, so, taking the time to do the motions right -- and
2 I'm especially -- you know, the, the proximate cause motion
3 is not just one motion because all of the three, all of the
4 three defendants touched on proximate cause individually in
5 addition to the global motion.

6 And the 71-page brief that Ms. Mainigi just filed is,
7 is a very complicated one. It is something that's going
8 to -- and raises completely new issues in the litigation
9 undoing further rulings that Your Honor has already made or
10 attempting to. And, you know, I think it's a real motion.
11 I'd like the time to do the research and get that stuff
12 right.

13 MS. MAINIGI: Your Honor, we do think -- these are
14 very serious motions, as Your Honor recognized from the
15 arguments yesterday, and they definitely deserve the
16 attention of this Court when the Court has the opportunity.

17 THE COURT: And having said that, that deserves
18 Mr. Majestro time to produce the kind of work product that
19 the defendants have produced which is -- all that will be
20 very helpful to me.

21 And I'm going to give you three weeks, Mr. Majestro.

22 MR. MAJESTRO: I think we can make that work. I
23 appreciate it, Your Honor.

24 THE COURT: Three weeks from, three weeks from --

25 MR. MAJESTRO: Today.

1 THE COURT: Three weeks from today. And we're
2 going to finish the evidence if we stick to the original
3 schedule and take a couple weeks off and then come back for
4 final arguments. But this briefing, I would think, will
5 certainly facilitate the consideration of the issues that
6 will be argued in the final arguments if we get that far.

7 MS. MAINIGI: Your Honor, with respect to that --
8 again, we can discuss this later this afternoon or when we
9 return. The defendants would, depending on the timing,
10 would really like to fit in final arguments in July if that
11 is possible.

12 And the reason for that, candidly, is various of us --
13 many of us will have to move onward to trial in September in
14 Washington state, and we'd like to spend August with our
15 families and take vacation and all of that. And, so, we
16 will certainly work consistent with Your Honor's schedule.

17 THE COURT: Well, let's see where we get. And
18 finishing by the end of July would certainly be welcomed by
19 the Court.

20 MS. MAINIGI: I think it would be welcomed by
21 everybody in this courtroom, Your Honor. But we, we can
22 address that later. And we can even propose a schedule to
23 the Court and the plaintiffs, if that makes sense to, to
24 you.

25 And it looks like we've decided a date. We would just

1 ask if the plaintiffs are able to get the briefs done on a
2 rolling basis, I think that would certainly help everybody
3 to have that happen within the three-week period.

4 MR. MAJESTRO: I mean, to the extent that's
5 possible. I, I anticipate filing -- I'm going to -- some of
6 them are overlapping in the sense that they're the same
7 argument with different factual bases. So some of them are
8 going to be -- one response will go to multiple motions.

9 So to the extent we can do that, I'm happy to. But I
10 can't make any promises here until we've gotten further into
11 it.

12 THE COURT: Okay. Well, you've got three weeks,
13 Mr. Majestro.

14 MR. MAJESTRO: Thank you, Your Honor.

15 THE COURT: And I look forward to your work
16 product. And we need to get Dr. Gilligan on and off.

17 MR. SCHMIDT: Your Honor, just -- just as a matter
18 of housekeeping, Your Honor, before the break we had
19 submitted the timeline that we spent building with Dr.
20 Gilligan as a court exhibit. I just put a sticker on it for
21 official purposes, if I may submit it as McKesson
22 Demonstrative 11.

23 THE COURT: All right.

24 You may resume the stand, Dr. Gilligan.

25 BY MR. SCHMIDT:

1 Q. Good afternoon, Dr. Gilligan. I'll pick up where
2 we left off. We walked through --

3 MR. SCHMIDT: And, and could we just put up the
4 timeline just to orient us very quickly, McKesson
5 Demonstrative 11, if that's possible?

6 BY MR. SCHMIDT:

7 Q. So we walked through these various statements from
8 the national groups, West Virginia Board of Medicine,
9 took us up until 2013 with the West Virginia Board of
10 Medicine, repeated a statement about prescription
11 opioids being essential in certain instances in the
12 treatment of acute pain and certain types of chronic
13 pain.

14 Since that time, has the standard of care for
15 prescription opioids continued to evolve?

16 A. Yes, it has.

17 Q. And, and how has that impacted prescribing rates in the
18 time period since we were walking through?

19 A. So in the time period since what we walked through, it
20 has gotten more conservative.

21 Q. Uh-huh.

22 A. And accompanying that, prescribing rates have gone
23 down.

24 Q. From your perspective, has that been driven by the
25 medical profession?

1 **A.** Yes.

2 **Q.** And if you could characterize the state of prescribing
3 today, how would you characterize that in terms of
4 prescription opioids?

5 **A.** So it's significantly more conservative than the
6 mind-set in many of the years, or in the years shown there,
7 certainly many of the years shown there, with more awareness
8 of the potential ill effects, adverse effects from
9 medications, risks of the medications for patients, a
10 greater weighting on that, and also with more skepticism
11 about the benefits.

12 Again, you know, some patients do well, but a rise in
13 awareness that many patients won't benefit from them so,
14 therefore, a shifting of the risk benefit.

15 **Q.** Okay. Mindful of what you just said, are prescription
16 opioids still prescribed today for acute pain, just more
17 narrower perhaps?

18 **A.** Yes, they are.

19 **Q.** Are they still prescribed for cancer pain?

20 **A.** Yes, they are.

21 **Q.** And, again, mindful of what you told us about the
22 science on non-cancer chronic pain and what you said just
23 now, are they still prescribed in certain instances for
24 non-cancer chronic pain?

25 **A.** Yes.

1 **Q.** I'd like to show you a document on some of these points
2 we've been talking about just now in terms of current
3 standards.

4 MR. SCHMIDT: May I approach, Your Honor?

5 THE COURT: Yes, you may.

6 BY MR. SCHMIDT:

7 **Q.** And just to orient us as to what we're looking at,
8 this is Defense West Virginia 2527. If we look at the
9 top of the document, we see the AMA logo, the date
10 June 16th, 2020. And it looks like it's written to the
11 Chief Medical Officer of the U.S. Centers for Disease
12 Control and Prevention. Do you see that?

13 **A.** Yes, I do.

14 **Q.** Are you familiar with this letter from the AMA?

15 **A.** Yes, I am.

16 MR. SCHMIDT: Your Honor, we move this into
17 evidence for the limited purpose of notice.

18 THE COURT: Any objection?

19 MR. FARRELL: Yes, Your Honor. I'm not quite sure
20 how an expert witness is able to lay the foundation for a
21 document written by somebody else and sent to a third party
22 about a subject matter that he was not involved in with the
23 drafting or writing of this letter. Sure, he can testify to
24 it all he wants, but this isn't a vehicle to be entering
25 into the record.

1 THE COURT: Can you lay a little better
2 foundation, Mr. Schmidt?

3 MR. SCHMIDT: Yeah, yeah, I'll do my best.

4 BY MR. SCHMIDT:

5 Q. First of all, do you understand this to be a
6 private letter that we somehow obtained or a public
7 letter?

8 A. I understand it to be a public letter.

9 Q. Do you understand this document to be publicly
10 available to members of the medical profession?

11 A. Yes, I do.

12 Q. And in terms of -- if we look at the first sentence of
13 this document, it says it's on behalf of the American
14 Medical Association and our physicians and medical student
15 members. Do you see that?

16 A. I do.

17 Q. When the AMA is writing on behalf of themselves and
18 their physician medical student members, who is that?

19 A. Well, the AMA, as we discussed, is the biggest
20 association of doctors in the U.S.

21 Q. And after they say that they're writing on behalf of
22 themselves and the physicians and medical student members,
23 they say the AMA appreciates the opportunity to --

24 MR. FARRELL: Objection, Your Honor. I didn't
25 make my first objection just to provide the opportunity to

1 read it into the record.

2 MR. SCHMIDT: I'm trying to lay the foundation as
3 to what the document is and why --

4 THE COURT: I'm satisfied with the foundation he's
5 laid so far.

6 Mr. Ackerman.

7 MR. ACKERMAN: Yeah. I am curious as to Mr. -- or
8 counsel offered the document for purposes of notice. My
9 question is notice of what to whom?

10 MR. SCHMIDT: Notice of the consensus in the
11 medical profession to doctors who are being spoken for on --
12 in this letter and to the healthcare system.

13 THE COURT: I'm going to admit it for the limited
14 purpose. We need to get through Dr. Gilligan here.

15 MR. SCHMIDT: Okay.

16 THE COURT: Go ahead, Mr. Schmidt.

17 MR. SCHMIDT: Thank you, Your Honor.

18 BY MR. SCHMIDT:

19 **Q.** I'll jump past -- well, actually, just to finish
20 this sentence, do you see that there's reference --
21 they're saying they appreciate the opportunity to review
22 and comment on the Centers for Disease Control and
23 Prevention guidelines for prescribing opioids for
24 chronic pain originally published in 2016.

25 **A.** I see that.

1 Q. Do you remember this morning you and I touched on those
2 CDC guidelines?

3 A. Yes, I do.

4 Q. Could you just remind us of the effect of those CDC
5 guidelines?

6 A. So the CDC guidelines laid out numerous steps
7 recommending essentially that doctors should be more
8 conservative, more cautious in their prescribing of chronic
9 opioid therapy for non-cancer pain.

10 Q. Okay. Go to Page 3 of the document, please, down at
11 the bottom. Do you see there's reference to AMA Task
12 Forces?

13 A. Yes, I do.

14 Q. "The Task Forces further affirm that some patients with
15 acute or chronic pain can benefit from taking prescription
16 opioid analgesics at doses that may be greater than
17 guidelines or thresholds put forward by federal agencies."
18 And then it lists other bodies. Do you see that?

19 A. I do.

20 MR. FARRELL: Objection, Your Honor. Again, this
21 is a letter by a third party written to another third party
22 that's being read into the record by a fourth party. If Dr.
23 Gilligan wants to testify what he believes to be the
24 standard of care, we have no objection. He's well
25 qualified. But neither Deborah Dowell nor James Madara have

1 been called into this courtroom.

2 THE COURT: Mr. Ackerman.

3 MR. ACKERMAN: Yeah. I would add that I don't
4 think reading this, this sentence is consistent with
5 admitting the document for a limited purpose. If it's a
6 limited purpose of notice, that's fine, but --

7 THE COURT: Well, I'll sustain the objection. But
8 you can ask him the questions without reference to the
9 document, Mr. Schmidt.

10 BY MR. SCHMIDT:

11 **Q.** Do you, do you --

12 MR. SCHMIDT: Where I was going, Your Honor --

13 THE COURT: If I understand it.

14 MR. SCHMIDT: Yeah. What I was going to ask him
15 was does he understand this to be the standard of care.

16 BY MR. SCHMIDT:

17 **Q.** So do you understand the standard of care in the
18 medical profession to reflect that patients with acute
19 or chronic pain, some patients can benefit from taking
20 prescription opioids at doses that may still be greater
21 than guidelines or thresholds set by the Federal
22 Government or other agencies?

23 **A.** Yes, I do understand that to be the consensus within
24 the standard of care.

25 **Q.** And last question about this document. If we go to the

1 first page, in the last paragraph on the first page there's
2 language about the nation no longer having a prescription
3 opioid-driven epidemic. What we're now facing is a
4 different --

5 MR. ACKERMAN: Objection.

6 THE COURT: You're doing the same thing that I
7 sustained the objection to.

8 BY MR. SCHMIDT:

9 Q. Do you have an understanding, sir, as to whether --

10 MR. ACKERMAN: I'd ask that the portion that we
11 just objected to be taken off the screen.

12 MR. SCHMIDT: It's off the screen.

13 BY MR. SCHMIDT:

14 Q. Do you have an understanding as to whether the
15 nature of, of drug abuse involving opioid products has
16 shifted from prescription drugs to illegal heroin and
17 fentanyl over the past decade?

18 A. Yes, I do.

19 Q. And what, what is that understanding?

20 A. That it has shifted in that way, that it has shifted
21 from abuse and misuse of prescription opioids to abuse and
22 misuse of heroin and fentanyl and fentanyl analogues that
23 are illicit fentanyl, not, not pharmaceutical fentanyl.

24 Q. Just a few questions to round out our, our time
25 together.

1 As a prescribing physician covering the time period
2 we've been talking about, including the increase in
3 prescriptions and then the decrease in prescriptions, do you
4 have an opinion as a prescribing physician as to which
5 healthcare decision-makers in the healthcare process drove
6 those changes in prescribing in both directions?

7 **A.** Yes, I do.

8 **Q.** What is that?

9 **A.** Physicians and other prescribing clinicians.

10 **Q.** And from your experience, when we were at the peak or
11 moving up to the peak or coming back down, do you have an
12 understanding as to whether that prescribing was driven by
13 good faith medical decisions?

14 **A.** Yes. I think the great majority of the
15 over-prescribing was well-intentioned. The majority of
16 opioid prescribing during much of that period, or perhaps
17 all of that period was by primary care physicians.

18 And, so, I think there was a great majority of cases of
19 well-intentioned clinicians trying to follow what they
20 understood, or in some cases what they had been told, was
21 the right way to treat patients.

22 **Q.** Do you have a view as to whether distributors drove
23 prescribing decisions by doctors in terms of their
24 understanding of risks and benefits?

25 **A.** I do.

1 Q. What's that opinion?

2 A. I don't think distributors had an influence on doctors'
3 prescribing decisions.

4 Q. As someone who's had occasion to prescribe medication
5 and prescription opioids throughout your career, have you
6 ever done so based on interactions with a pharmaceutical
7 distributor?

8 A. No, I have not.

9 Q. In your experience, do distributors -- your experience
10 in the real world dealing with other doctors, do
11 distributors play a role that's meaningful in determining
12 how many prescriptions for opioids or any other product get
13 written in a given point in time?

14 A. No, they do not.

15 Q. That's all I have, Dr. Gilligan. Thank you.

16 THE COURT: All right. You may cross-examine.

17 CROSS EXAMINATION

18 BY MR. FARRELL:

19 Q. Good afternoon. I introduced myself earlier. I'm
20 Paul Farrell on behalf of the County Commission and City
21 of Huntington plaintiffs in this case.

22 I want to take this opportunity to use your expertise
23 to maybe crystalize or clarify some of the concepts that
24 we've talked about over the past several weeks.

25 We've inartfully used a phrase of a gateway effect. Is

1 that terminology something that you're familiar with?

2 **A.** Yes, it is.

3 **Q.** So -- and I'm very confident that you're familiar with
4 the idea and the medical side of it. But from a layman's
5 standpoint or a lawyer's standpoint, gateway effect is
6 intended to communicate that one thing transitions to
7 another.

8 What is your understanding of the meaning of gateway
9 effect?

10 MR. SCHMIDT: And I'll just object to the preamble
11 statement.

12 THE COURT: Overruled.

13 You understand the question, don't you, Dr. Gilligan?

14 THE WITNESS: I think I do.

15 THE COURT: Okay. Go ahead.

16 THE WITNESS: So I think the gateway effect is
17 when somebody in the context of substance abuse, when
18 somebody goes from one substance to another substance.

19 BY MR. FARRELL:

20 **Q.** So we've had testimony about a lot of articles and
21 I want to ask you a couple of them by name just to see
22 if you recognize them. It's not a test. But Muhury,
23 M-u-h-u-r-y, was addressed earlier. And you're familiar
24 with that?

25 **A.** Yes, I am.

1 Q. And what about Compton, the Compton article in the New
2 England Journal of Medicine? Are you familiar with that?

3 A. I believe I am, yes.

4 Q. And then most recently there's been another article by
5 McCabe, M-c-C-a-b-e. Are you familiar with that article?

6 A. I'd have to see a specific article to know. There
7 might be more than one McCabe article.

8 Q. This is very true. This is 2021 in the Journal of
9 Addiction Medicine entitled "Pills to powder, a 17-year
10 transition from prescription opioids to heroin among U.S.
11 adolescents followed into adulthood."

12 I'm not going to -- I'm just asking are you generally
13 familiar with that article?

14 A. I, I don't remember. I've looked at so many articles,
15 I just don't remember.

16 Q. Okay. So let me see if I can read some of the concepts
17 and see if we can agree to it.

18 First of all, you recognize that the Journal of
19 Addiction Medicine is an authoritative text in the field of
20 the treatment of pain?

21 A. The Journal of Addiction Medicine is a medical journal
22 in the field of addiction medicine. I don't -- I'm not sure
23 when you're saying authoritative text exactly what the
24 definition is there.

25 Q. That's a legal ease term. Is the Journal of Addiction

1 Medicine one in which physicians like yourself would rely or
2 use to educate themselves on the state of art of the
3 standard of care?

4 **A.** The Journal of Addiction -- it's one of the medical
5 journals that people in my field might read. It's a
6 peer-reviewed journal, yes.

7 **Q.** Pardon me. I need my spectacles.

8 So in this 2020 article it makes reference to Muhury
9 and Compton and it says this. And I'd like to ask you
10 whether or not you agree with it.

11 "Although the vast majority of prescription opioid
12 exposure does not lead to heroin use, heroin incidence and
13 prevalence rates were significantly greater among those who
14 reported non-medical prescription opioid misuse."

15 THE COURT: Mr. Schmidt.

16 MR. SCHMIDT: My objection is just if we're going
17 to read language that's specifically linked to an article, I
18 think it's fair to give the article to the witness.

19 THE COURT: Well, let's see where we go with this
20 without doing that.

21 And then if you need to refer to the article, Dr.
22 Gilligan, we'll get you the article.

23 THE WITNESS: Thank you.

24 MR. FARRELL: I have to acknowledge, Judge, in my
25 20 years of doing medical malpractice litigation, this is

1 the first time my opposing counsel has asked me to share the
2 medical literature, but I have it with me.

3 THE WITNESS: Thank you.

4 BY MR. FARRELL:

5 Q. I'm even going to see if I can put it up on the
6 screen.

7 Do you see the paragraph -- I'm going to, I'm going to
8 kind of see if I can draw a line on it. This is insane.
9 Now that I want to use it, I can't draw a line on it.

10 But if you see the paragraph, it says "the percentage
11 of people." Do you see that?

12 A. I think so. The second paragraph?

13 Q. Yes. Just to orient you, if you look at the title of
14 the document -- at the top -- the bottom left-hand corner it
15 has the journal reference. You're familiar with the format
16 of these journal articles?

17 A. Yes, I am.

18 Q. And what I want to particularly ask you about is the
19 sentence by sentence. I'm going to highlight it right here.
20 And I hope I can tie it all together to make sense at the
21 end. But do you see the sentence I highlighted?

22 A. More or less I can see it on the, on the screen up
23 front here. I can't see it perfectly, but I think I have a
24 sense of which one you highlighted.

25 MR. FARRELL: Okay. I wish I had just read it,

1 Judge. All right. So it's highlighted there.

2 BY MR. FARRELL:

3 **Q.** "Although the vast majority of prescription opioid
4 exposure does not lead to heroin use, heroin incidence
5 and prevalence rates were significantly greater among
6 those who reported non-medical prescription opioid
7 misuse."

8 And the footnotes, I'll represent to you, are to Muhury
9 and Compton.

10 Do you agree that's a fair reflection of what Muhury
11 and Compton would say?

12 **A.** I think that that's one of the points that was raised
13 in the Muhury article.

14 **Q.** And do you agree that that's the state of medical
15 knowledge or an accepted position taken by physicians in
16 your field?

17 **A.** I, I think that -- I personally think that that is a
18 fair statement, yes.

19 **Q.** All right. So the very next sentence says, "Based on
20 retrospective data --" what is retrospective data?

21 **A.** So that's data where you do your study by looking
22 backwards rather than organizing a study that will look --
23 that you say from here going forward we will collect data
24 and interpret it. Generally, prospective studies are
25 considered a higher grade of science in the majority of

1 cases than retrospective.

2 **Q.** So the reference at the end of this sentence, I'll
3 represent that's Muhury again. And it says, "Based on
4 retrospective data, only one percent of individuals who
5 reported past-year non-medical prescription opioid misuse
6 had used heroin before using prescription opioids."

7 Do you see that sentence?

8 **A.** I do.

9 **Q.** And I'm going to try to recapture that in normal words.
10 Does that basically mean that, that based on this study
11 looking backwards in time that only one percent of the
12 population of heroin users were using heroin before they
13 were abusing prescription opioids?

14 **A.** Yes. Only one percent of them had past-year
15 non-medical prescription opioids had used heroin before
16 misusing prescription opioids.

17 **Q.** And just from a common sense standpoint, in general
18 people are more likely to abuse opium in the powder form
19 before taking opium with a needle. Is that your experience?

20 **A.** I think that people -- some individuals definitely are
21 more likely to use other forms of opioids prior to injecting
22 if they're misusing or abusing them, yes.

23 **Q.** And what Muhury is saying is that, that based on this
24 retrospective study, that the number of people that had used
25 heroin first is one percent?

1 **A.** That in their study the number of people who used
2 heroin prior to non-medical use of prescription opioids was
3 one percent.

4 **Q.** And then the rest of that sentence says, "Whereas
5 approximately 80 percent of those who reported past-year
6 heroin use had misused prescription opioids before starting
7 heroin."

8 Did I read that correctly?

9 **A.** Yes, you did.

10 **Q.** And is that a fair depiction of Muhury's conclusion?

11 **A.** I think it's partially fair, but I think it's also
12 somewhat incomplete.

13 **Q.** Okay. What would be the more complete version?

14 **A.** That 80 percent of those who used the heroin had
15 engaged in misuse or abuse of non-medical use of
16 prescription opioids, but that a similar number had also
17 used illicit drugs prior to that.

18 **Q.** Right. So -- but in general, it's a true statement
19 that four out of five heroin users began abusing
20 prescription opioids before initiating heroin based on the
21 current state of medical literature. Agreed?

22 **A.** That is what the Muhury, Muhury's article states, yes.

23 **Q.** Yes. I'm asking you whether you agree with that.

24 **A.** Yes, I do.

25 **Q.** And do you have any reason to -- any reasonable dispute

1 with the truth of that?

2 **A.** I don't have a reason to dispute it, no.

3 **Q.** Now, this McCabe article that I'm showing you got a
4 little bit of acclaim because Dr. Compton who is at the NIH
5 even wrote an editorial in the Journal of Addiction
6 Medicine, a commentary. Have you had a chance to review his
7 commentary or were you aware that Dr. Compton endorsed the
8 McCabe article?

9 **A.** I think I'd have to look at the article in question to
10 remember, frankly. Again, I've looked at so many articles
11 on these topics.

12 **Q.** Does it really matter, though, if somebody -- if
13 Dr. Compton, even if he's in NIH, does it matter if he
14 agrees with it or not in your opinion? Does it give it
15 weight?

16 **A.** It might.

17 **Q.** Okay.

18 MR. FARRELL: Judge, may I?

19 BY MR. FARRELL:

20 **Q.** I'll give you a chance to take a peek at it. I
21 don't have a whole lot -- I mean, I can go through it
22 with you, but I'll represent to you that it appears to
23 be an acknowledgment by Dr. Compton applauding the first
24 prospective study in your field of medicine regarding
25 the gateway effect. Is that a fair and accurate

1 depiction of Dr. Compton's commentary?

2 **A.** I think I, I would, frankly, have to read through it to
3 assess if it's a fair and accurate summary of it.

4 **Q.** Okay. Well, how about we go and look at the very first
5 paragraph, just go down to the middle of it where it says
6 "Key Findings."

7 It says, "Key findings include an overall association
8 of both non-medical and medical use of opioid analgesics
9 with transition to heroin use with particular concerns about
10 early non-medical use."

11 This is, this is Dr. Compton's interpretation of the
12 McCabe article. So do you have any reason to dispute the
13 key findings of the McCabe article that I showed you?

14 **A.** I, I don't have a reason to dispute the findings, no.

15 **Q.** Okay. Well, I guess I'm just trying to fish around to
16 see whether or not you give weight to Dr. Compton's
17 commentary before we get into the McCabe article.

18 **A.** Yes. But, again, I'd have to read through it. It's
19 not a very long article, but I'd have to read through it to
20 have a full opinion on it.

21 **Q.** That's fair. Why don't we just go straight to the
22 McCabe article.

23 If we can go to Page 3 of the McCabe article, under the
24 discussion section, the very first sentence says, "This is
25 the first national prospective study to examine the

1 relationships between adolescents' prescription opioid use
2 and misuse and subsequent heroin use over a 17-year period."

3 So do you understand what that sentence means, that
4 description of the study?

5 **A.** Yes, I do.

6 **Q.** And does that give you, having looked at it now, any --
7 I'm trying to lead you -- any recollection as to what this
8 article is or whether or not you've read it before?

9 **A.** I believe that I have read it before. And I think
10 it's -- what, what it describes is a prospective look at
11 this question of prescription opioid misuse, abuse, use and
12 individuals who initiate heroin use.

13 **Q.** Does this article have weight in your field?

14 **A.** I think it has some weight, yes.

15 **Q.** Basically, what they did was they studied -- over a
16 period of 17 years, they studied over 11,000 high school
17 kids and tracked them to age 35 and looked at and measured
18 the relationship between those that have used and were
19 prescribed prescription opioids and those that initiated
20 heroin. Agreed?

21 **A.** Yes. Again, in an article like this, there's quite a
22 bit of detail. So there may be many different points. But
23 I think that's one of the things that it covers, yes.

24 **Q.** And what it found was that it wasn't four out of five.
25 What it found was that nearly one -- it went in the other

1 direction with initiation. It said nearly one in three
2 adolescents who reported non-medical prescription opioid
3 misuse went on to report heroin use.

4 This article stands for the proposition that there's a
5 greater relationship between abusing medical prescription
6 opioids -- I'm sorry -- that there's a greater relationship
7 between non-medical use of opioids and initiation of heroin
8 than we ever thought. That's the conclusion of this
9 article. Agreed?

10 MR. SCHMIDT: Objection, compound and
11 characterization.

12 THE COURT: Well, I'll sustain the objection. You
13 can try again, Mr. Farrell.

14 BY MR. FARRELL:

15 **Q.** Dr. Gilligan, did you understand my question?

16 **A.** I think so. Could you repeat the question, please?

17 **Q.** Yes. I'm going to try to repeat it in simpler terms.

18 This article, this, this McCabe article stands for the
19 proposition that abusing prescription opioids has a much
20 higher relationship to the initiation of heroin than the
21 medical community had ever thought before. Agreed?

22 **A.** I think, again, I'd have to read through the, the
23 article to make a real statement about what all of its
24 conclusions are.

25 **Q.** Okay. Sir, have you read the book Dreamland?

1 **A.** Yes, I have.

2 **Q.** And in Dreamland it too talks about the sequencing of
3 prescription opioids to heroin, does it not?

4 **A.** Among other things, yes.

5 **Q.** So I guess ultimately what I'm asking is this. If a
6 community is overwhelmed or flooded with prescription
7 opioids -- assume that to be a fact. I know it may be
8 disputed. But let's just in a fictional world take
9 81 million pills and drop it into a community of 100,000
10 people. Would you expect that community to see a higher
11 incidence of heroin initiation over time?

12 **A.** I think if there are a large number of medications
13 prescribed in any area, there will be some of them that will
14 be diverted, misused, abused. And, so, that there would be
15 some incidence then where that diversion leading to misuse
16 abuse, there would be some instances where that would lead
17 to someone initiating heroin. I think that would be
18 statistically likely in any area with a large number of
19 opioid pain medications that were prescribed.

20 **Q.** And, so, when you look at it from a statistical
21 standpoint, as the number or the volume of pills would grow
22 higher per capita, would you also expect there to be a
23 parallel increase in diversion and heroin initiation?

24 MR. SCHMIDT: Objection, foundation.

25 THE WITNESS: I think a process --

1 THE COURT: Just a minute. Overruled.

2 If you understand the question, you can answer it, Dr.
3 Gilligan.

4 THE WITNESS: I think I understand it.

5 I think it could be in line with what's in that book
6 Dreamland, but I think it would be very, very
7 multifactorial.

8 BY MR. FARRELL:

9 Q. Sure.

10 A. So, I mean, that book Dreamland talked about changes
11 and how heroin got distributed, talked about socioeconomic
12 risk factors, also talked about volume of prescribing. So I
13 think those sort of processes by their nature are very, very
14 multifactorial.

15 Q. Is that called -- in pharmaceutical terms is that
16 compounding? Is that -- these factors sometimes compound on
17 top of each other?

18 A. No. Compounding in pharmaceutical is something very
19 technical. It's when they essentially sort of make a custom
20 medication for you.

21 Q. Now, you do recall that Dreamland is premised in the
22 Ohio River Valley?

23 A. I do.

24 Q. And you're actually in the Ohio River Valley today.

25 A. Correct.

1 **Q.** And that Dreamland is the name of a pool in Portsmouth,
2 Ohio, which if you hopped in the Kanawha River here you
3 would float down to it?

4 MR. RUBY: Your Honor, I'm not sure of the
5 relevance.

6 THE COURT: Where are you going with this, Mr.
7 Farrell?

8 MR. FARRELL: I'm getting there soon. I'd ask for
9 just a little bit of leeway to try to establish prescribing
10 patterns.

11 THE COURT: Well, I'll sustain the objection to
12 the last question but --

13 MR. FARRELL: Judge, to be --

14 THE COURT: You said Dreamland is the name of a
15 pool which if you hopped into the river, bla, bla, bla. I
16 sustain the objection to that portion.

17 BY MR. FARRELL:

18 **Q.** So to eliminate any debate in this courtroom, you
19 agree and embrace the gateway effect that there does
20 exist in scientific terms a relationship, a direct
21 relationship between the use and abuse of prescription
22 opioids and initiation of heroin?

23 **A.** I think there's a direct relationship that includes the
24 misuse and abuse of prescription opioids, along with many
25 other predisposing factors that, that then does relate to

1 initiation of heroin.

2 **Q.** So the gateway effect is true?

3 **A.** Again, there, there is a transition that can occur that
4 includes many factors including misuse and abuse of
5 prescription opioids, along with other risk factors that can
6 lead to the initiation of heroin.

7 **Q.** Dr. Gilligan, do you recall giving a presentation in
8 2014, The Interventionalist's Perspective on Psychology and
9 Outcomes?

10 **A.** Yes, I do.

11 **Q.** I have your slide deck.

12 MR. FARRELL: Judge, if I may, I'd like to
13 approach.

14 THE WITNESS: Thank you.

15 BY MR. FARRELL:

16 **Q.** Dr. Gilligan, do you recognize this document?

17 **A.** Yes, I do.

18 **Q.** What is it?

19 **A.** It's a slide deck from a presentation that I gave to a
20 group of physicians at a conference on pain medicine.

21 **Q.** And did you prepare this document?

22 **A.** Yes, I did.

23 **Q.** Did you intend this document to be educational for the
24 purposes in which you presented it?

25 **A.** Yes, I did.

1 MR. FARRELL: Judge, we'd ask for P-41958 to be
2 admitted into the record.

3 THE COURT: Is there any objection?

4 MR. SCHMIDT: Yes, there is, Your Honor. It's
5 hearsay. I think they're trying to impeach him with it.
6 That's just impeachment.

7 THE COURT: I'm not going to admit it, Mr.
8 Farrell, but you can use it as a basis to question about
9 what's in it.

10 MR. FARRELL: Judge, respectfully, if I can create
11 a record, it's not hearsay. And if it is, it falls within
12 the catch-all because the author of the document is sitting
13 in the chair. And any confusion or any question about the
14 veracity of the document can be raised with the author who's
15 sitting in the chair.

16 THE COURT: What are you referring to as the
17 catch-all, Mr. Farrell?

18 MR. FARRELL: 807.

19 THE COURT: Okay, residual exception.

20 MR. FARRELL: Yes, sir.

21 MR. SCHMIDT: Your Honor, my understanding is
22 we've previously dealt with this issue. We dealt with this
23 issue with Dr. O'Connell when she testified when we tried to
24 use some of her slides. And I think Your Honor said they
25 could be used for impeachment but not admitted into the

1 evidence. We think the same ruling should apply here.

2 MR. RUBY: And, Your Honor, if you look, Judge, at
3 807(b) there's a notice requirement there in that rule that
4 I don't believe has been satisfied unless the notice was
5 given to Mr. Schmidt.

6 MR. SCHMIDT: No, it wasn't.

7 MR. FARRELL: I'll withdraw it, Judge, and we'll
8 just show it up on the screen.

9 BY MR. FARRELL:

10 **Q.** Dr. Gilligan, there's a Bates stamp that is
11 artificially created by our numbering system. I'd like
12 for you to go look at the bottom right-hand page which
13 is -- it says P-41958 and then it's actually Page 29, so
14 the underscore 00029. I have it up on the screen if
15 you'd like to use the screen.

16 MR. SCHMIDT: Your Honor, if it's not being
17 admitted, then it should be used for impeachment as opposed
18 to showing it to him and walking through it.

19 THE COURT: Well, this is cross-examination. I'm
20 going to allow it.

21 Go ahead, Mr. Farrell.

22 BY MR. FARRELL:

23 **Q.** Dr. Gilligan, did you prepare this slide? It says
24 "Rising Sales, Abuse and Deaths."

25 **A.** Yes, I did.

1 **Q.** Okay. Would you tell the Judge what this slide means
2 and what the purpose of this slide was?

3 **A.** So this was shown to change over time and sales of
4 prescription opioids which, which correlates with
5 prescriptions of opioid pain medications. That's the green
6 line.

7 The purple line is deaths from drug overdoses. And the
8 orange line is admissions for treatment of addiction.

9 **Q.** And what conclusions, if any, can you draw from these
10 three trends?

11 **A.** So the conclusion that I can draw is that as
12 prescriptions went up, deaths and treatment for addiction
13 went up as well.

14 **Q.** And so what, what -- how would you describe that
15 relationship? What's the point of putting this slide in
16 your slide deck?

17 **A.** The point is that over-prescribing by doctors
18 correlated with an increase in treatments for addiction and
19 with an increase in overdoses.

20 **Q.** And to be fair, it doesn't say "over-prescribing." You
21 used a different word, did you not?

22 **A.** I used the word that the CDC -- this is a graphic from
23 the CDC and they use "sales." But with a prescription
24 medication, sales is prescriptions. They're one for one.

25 **Q.** Well, that's not exactly true, is it? A prescription

1 is one prescription on a pad. This is tracking sales by
2 kilogram, is it not?

3 **A.** It's number of prescriptions that -- not a kilogram or
4 a gram of the medication leaves the pharmacy without a
5 prescription. So prescription medication sales how to be
6 measured correlates with prescriptions for that medication.

7 **Q.** I'm sorry. I think we're speaking past each other.
8 The measurement on this is by kilogram of the pills, not by
9 the number of written prescriptions?

10 **A.** Oh, correct. The unit that CDC used was, was, was
11 sales per kilogram, yes.

12 **Q.** All right. Now, if you go to the very next page, this
13 is Bates stamp Page 30. Will you describe what this slide
14 is and why you included it in your slide deck?

15 **A.** Sure. So this is showing similarly where there was a
16 lot of prescribing. This is obviously a map of the U.S.
17 where the dark green is, dark green is where there was more
18 prescription of pain, opioid painkillers. And the dark
19 purple is where there were more drug overdose deaths. And
20 it's showing geographically where there was more
21 prescribing, there were more deaths.

22 **Q.** And, so, this is Slide Number 30. And since it's not
23 in the record, I'm going to use some descriptive words so
24 that we have a written record of this.

25 The top of this says "Deaths Track Sales." Correct?

1 **A.** Correct.

2 **Q.** And the first top half of the screen is the United
3 States of America by, by state. And can you read aloud what
4 the words are that you wrote on this slide for the green
5 map?

6 **A.** Sure. Actually, I took the map from CDC. So it's
7 words that they wrote. "Amount of prescription painkillers
8 sold by state per 10,000 people 2010."

9 **Q.** And then on the bottom half there's the purple map with
10 the purple United States. Will you read what the tag line
11 is for that?

12 **A.** "Drug overdose death rates by state per 100,000 people
13 2008."

14 **Q.** And, so, what was the point of putting in one map
15 tracking sales and in a second map tracking deaths?

16 MR. RUBY: Your Honor, I'm going to interpose an
17 objection with regard to scope. The witness's testimony on
18 direct examination went to the change in the standard of
19 care that occurred in the medical field for prescription
20 opioids and the cause of the standard of care.

21 Asking him to testify about, about these slides titled
22 "Deaths Track Sales" or slides along those lines, that's
23 beyond the scope of his direct testimony.

24 THE COURT: Well, what's your response to that,
25 Mr. Farrell?

1 MR. FARRELL: I strongly disagree.

2 MR. ACKERMAN: Your Honor, I would further note
3 that we have made numerous scope objections in our part of
4 the case and you have said if there is a good faith basis to
5 question the witness on cross-examination that the
6 defendants can go ahead.

7 And, certainly, Mr. Farrell has a good faith basis to
8 cross-examine a witness who is testifying about the opioid
9 epidemic based on a slide deck that the witness put together
10 that describes the opioid epidemic.

11 MR. RUBY: Your Honor, I just -- with respect to
12 Mr. Ackerman, I don't believe that there was any ruling in
13 the -- during the plaintiffs' case during our
14 cross-examinations that, that the principle of scope was out
15 the window.

16 THE COURT: Well, I'm going to overrule the
17 objection. You can go ahead, Mr. Farrell.

18 MR. FARRELL: Thank you.

19 BY MR. FARRELL:

20 **Q.** So I think the last question I asked was what, what
21 point were you trying to communicate by putting the
22 green map in sales and comparing it to the purple map in
23 deaths?

24 **A.** So I was trying to teach the doctors who were at the
25 conference that where there is more opioid prescribing

1 geographically, where doctors prescribe more opioids, there
2 tends to be more overdose deaths in those same areas.

3 **Q.** Now --

4 **A.** And where there's less prescribing, there are less
5 deaths.

6 **Q.** Let me -- let's try to be accurate here on this very
7 important point. What you were trying to demonstrate by
8 using kilograms per capita was that the weight of
9 prescription opioids sold in particular locations had a
10 direct relationship to deaths. Correct?

11 **A.** No, incorrect. That's not what I was trying to teach.
12 I was trying to teach the doctors that where you prescribe
13 more opioids, there are more deaths, and where you prescribe
14 less opioids, there are less deaths. It was an audience of
15 doctors and that's what I was trying to teach them.

16 **Q.** I don't, I don't want to parse words with you. But the
17 measuring stick in the green map is kilograms of
18 prescription opioids, and that in states that had the more
19 weight by kilogram per capita have a darker color. Correct?

20 **MR. SCHMIDT:** I think we've asked and answered
21 this a few times, Your Honor.

22 **THE COURT:** I think it is. I'll sustain the
23 objection. But I think this is relevant. I think this goes
24 to -- it's proper cross-examination related to his testimony
25 about the changes in the standards of care and the reasons

1 for it and so forth. This is consistent with his testimony
2 concerning the reason for the change in the standard. So I
3 think at least to that extent, it's relevant and proper
4 cross-examination.

5 MR. FARRELL: But you'd like me to move on?

6 THE COURT: Yes. I sustain the last objection.
7 I'm explaining my reasons for ruling in your favor the last
8 time.

9 MR. FARRELL: I'm catching up.

10 THE COURT: Okay.

11 MR. FARRELL: It took nine weeks but --

12 BY MR. FARRELL:

13 **Q.** So if we flip to the next slide, which is Bates
14 stamp 31, and when you look at this slide, down here at
15 the bottom it says "Policy Impact Prescription
16 Painkiller Overdoses," the CDC website. Do you remember
17 where you got this picture from?

18 **A.** Yes. I got it from the CDC -- from their website or
19 one of their documents.

20 **Q.** Okay. Is this a particular report or document? I
21 didn't understand what the policy impact reference was.

22 **A.** Oh, I, I, I'm almost certain that that is from the CDC
23 from their website and I think this might have been a report
24 that they, that they had on their website as best I can
25 recall.

1 Q. Okay. And would you please describe for the Judge what
2 you were trying to communicate with this picture?

3 A. So what I was trying to demonstrate with that picture
4 is that there are issues, adverse effects related to
5 over-prescribing that went beyond just deaths; that when
6 there's over-prescribing, deaths are a concern but there are
7 other concerns and those are shown here.

8 Q. So is it fair to say that what you were trying to
9 depict is that for every one death, you could expect to see
10 10 treatment admissions for abuse?

11 A. Correct.

12 Q. And for every one death, you could expect to see 32
13 emergency department visits for misuse or abuse?

14 A. Yes.

15 Q. And that for every one death, you would expect to see
16 130 people who abuse or are dependent?

17 A. Yes.

18 Q. And for every one death, you would expect to see 825
19 non-medical users?

20 A. Correct.

21 Q. Have you done any research to study how many deaths
22 happened in Huntington, Cabell County, West Virginia?

23 A. No, I have not.

24 Q. The next thing we're going to go to is --

25 MR. FARRELL: Gina, can you bring up the Seattle

1 lecture?

2 BY MR. FARRELL:

3 Q. You were in Seattle recently and gave a lecture,
4 did you not?

5 A. Not quite. I gave that lecture in -- at a conference
6 in Las Vegas. But the Seattle Science Foundation is the
7 group that chairs the lectures.

8 Q. I apologize. I saw Seattle down there and I just made
9 the assumption. Is this your slide deck from your
10 presentation?

11 A. I believe it is, yes.

12 Q. And, actually, that's not true. This isn't your slide
13 deck. This is a screen shot of the video. It's on YouTube.
14 Are you aware of that?

15 A. Yes, I am.

16 Q. And, so, it's got a lot of hits. The -- can you tell
17 the Judge who you were speaking to at -- during this
18 lecture?

19 A. So it was to a group of doctors and other clinicians.

20 Q. Was it well-attended? Was it a big event?

21 A. Yes, something like 200, 300, something like that.

22 Q. Okay. And the name of this is "Who's to Blame and
23 Who's to Pay for the Opioid Crisis?" Did you come up with
24 that title?

25 A. No. The organizers asked me -- gave me that title,

1 asked me to speak on that title.

2 **Q.** It happens to me all the time when they want something
3 catchy to get people's attention. This is your, this is --

4 **MR. SCHMIDT:** I would object to that
5 characterization.

6 **BY MR. FARRELL:**

7 **Q.** So I could play the 10 minutes because -- why did
8 you only have 10 minutes?

9 **A.** Again, that's the organizers.

10 **Q.** Yeah. I mean, it was fantastic, but it was 10 minutes.
11 I could play it but, instead, what I'm going to do is I'm
12 going to try to avoid objections by taking screen shots and
13 having you replicate it.

14 So if we can go to the next slide which is the first
15 slide that you began talking about. And do you recall
16 telling the panel or telling the group about this, this
17 slide?

18 **A.** Yes, I do.

19 **Q.** And, so, this slide is the first slide. And will you
20 describe what the slide is to the Court, to the Judge?

21 **A.** Sure. So it's showing over time in the U.S. the number
22 of drug overdose deaths. And the period is 1980 to 2018.
23 And then there are some other references -- we can all read
24 them -- peak car crash deaths, HIV deaths, and so forth.

25 **Q.** And, so, you, you made two comments in here that I'd

1 like to follow up on. One of them is you said that there
2 was a stark increase. Can you, can you talk to the judge
3 about the nature of this increase and why, if at all, --

4 MR. SCHMIDT: And we're not objecting, based on
5 Your Honor's prior rulings, to showing him the slides, but
6 just kind of characterizing statements that wouldn't be
7 admissible by themselves is not proper. If he wants to try
8 to ask him a question and try to impeach, I think that's
9 reasonable, Your Honor. But just characterizing what he
10 said is out of context.

11 THE COURT: You need to ask him the questions, Mr.
12 Farrell.

13 MR. FARRELL: Yes, Your Honor.

14 BY MR. FARRELL:

15 Q. Would you describe this chart as a stark increase?

16 A. It's definitely a very significant increase over time.

17 Q. Would you use the word yourself "stark," a stark
18 increase?

19 A. I might, yes.

20 Q. Okay. And then the number of people up here, can you
21 read that number?

22 A. 68,557.

23 Q. And you think that's enough people to fill an NFL
24 football stadium?

25 A. Yes, I do.

1 **Q.** All right. Let's go to the very next slide. This is
2 the next evolution in your presentation. And we're familiar
3 with these in this litigation. But what are we looking at
4 here?

5 **A.** So we're looking at the change in the incidence of drug
6 overdose deaths. And on the left we're comparing 2003. On
7 the right we're looking at 2017. And, again, as with some
8 of the others, the darker color is when there's a higher,
9 higher incidence or a higher rate.

10 **Q.** And you acquired this from the CDC website?

11 **A.** Correct.

12 **Q.** And it has not just 2003. It actually goes back
13 further than that, doesn't it?

14 **A.** Correct.

15 **Q.** And in each year there's a picture of the, of the
16 deaths that were reported in the United States. And when
17 you look from 2003 to 2017, what does it look like happened
18 in the Ohio River Valley?

19 **A.** The, the rate increased, or the incidence increased.

20 **Q.** Let's go to the next slide. Now, I think this is the
21 same slide that we talked about before; correct?

22 **A.** Or similar there, either the same or similar.

23 **Q.** Now, let's go to the next one because it's a little bit
24 different. Do you recall talking about this slide?

25 **A.** I do.

1 Q. All right. Would you please tell the Judge what this
2 slide depicts and why you created it?

3 THE COURT: Just a minute.

4 MR. SCHMIDT: I apologize. I should have asked
5 this before. Do you have a copy that we can have?

6 MR. FARRELL: Yes.

7 MR. SCHMIDT: I'd appreciate that.

8 MR. FARRELL: It has a bunch of them in there. It
9 may not be all of them that we use.

10 BY MR. FARRELL:

11 Q. Okay. So did you describe this as three waves?

12 A. I think I did.

13 Q. Yes. And, so, would you tell the Court what the first
14 wave was?

15 A. It is the prescription painkillers. It's the -- one of
16 the light pink lines that you see there.

17 Q. So the top, the top one I'm pointing to, that's the
18 first wave of prescription painkillers; correct?

19 A. Correct.

20 Q. And then what's the second wave?

21 A. It is the heroin.

22 Q. All right. And that would be this one here; correct?

23 A. Correct.

24 Q. And there is a stark increase in the heroin line
25 starting somewhere around 2010. Agreed?

1 **A.** There's a significant increase in the heroin line
2 starting around 2010, yes.

3 **Q.** And then you also said that there is this enormous
4 fentanyl spike that happens toward the later part of 2010.
5 Do you recall what you said about the origins of this and
6 how this came about?

7 **A.** I recall some of what I said. I don't know if I have a
8 complete recollection. It was a few years ago.

9 **Q.** Tell the Judge, if you would, how these three waves
10 interplay together, if you recall.

11 **A.** So one can see the time lines. One can see the years
12 at the bottom. And the overdose deaths from prescription
13 painkillers happened earlier. And then there was a
14 significant -- in many cases for people, there was a shift
15 and in other cases --

16 COURT REPORTER: I'm sorry?

17 THE WITNESS: In many cases a, a shift from
18 prescription painkiller abuse or misuse to abusing heroin
19 and/or a shift to, to illicit fentanyl.

20 BY MR. FARRELL:

21 **Q.** So is it fair to say that it's your opinion that
22 those that were suffering from opioid use disorder in
23 the first wave began to shift to heroin? Are those your
24 words?

25 **A.** They, they may well be.

1 Q. And the reason for the shift was because heroin was
2 more accessible and less expensive. Those are your words.
3 You've held that opinion, have you not?

4 A. I have held that opinion, yes.

5 Q. And that you again repeated on this stage that
6 80 percent of the people who were taking heroin had started
7 with prescription opioids. Is that -- those are your words;
8 correct?

9 A. Yes, they are.

10 Q. And you did not distinguish between medical and
11 non-medical. In fact you said, quote, "Now, that's either
12 prescription opioids that were prescribed to them or
13 prescription opioids that were diverted and they got their
14 hands on them."

15 Those were your words, were they not?

16 A. Yes.

17 Q. Now, do you recall your report in this case?

18 A. Yes, I do.

19 Q. And, so, you don't have it memorized I'm assuming. But
20 what I'd like to do is I'd like to reference one particular
21 provision. And that's on Page 23 where you make mention
22 of -- and I'll just read it to you.

23 "According to the CDC, opioid prescriptions peaked and
24 leveled off between 2010 and 2012 before beginning to fall
25 thereafter."

1 And then you say, "A similar pattern occurred in West
2 Virginia."

3 Do you recall making that statement?

4 **A.** Yes, I do.

5 **Q.** And you footnoted it. And one of the footnotes that
6 you referenced were trends and patterns from a JAMA network
7 article. Do you recall that?

8 **A.** More or less.

9 **Q.** I just have a couple of quick questions for you. I
10 want -- I'm going to read this provision to you and ask
11 whether or not you will agree with it for the Court.

12 MR. SCHMIDT: Your Honor, if he's going to read to
13 him from an article, I'd ask that we get a copy of it.

14 THE COURT: Can you give him a copy of it?

15 MR. FARRELL: I could. It's not the normal course
16 of how -- but, yes, I can.

17 MR. SCHMIDT: I think it's absolutely the normal
18 course that if you're going to represent documents to a
19 witness, the lawyer defending gets them.

20 BY MR. FARRELL:

21 **Q.** I'll withdraw that and just ask you a question and
22 see whether or not you agree to it. Okay? Here's my
23 question:

24 "Closing the path to opioid use disorder will require
25 addressing over-prescription of legal opioids, reducing the

1 availability of illicit opioids, and getting patients with
2 opiate use disorder into treatment."

3 Do you agree with that statement, sir?

4 **A.** Yes, I do.

5 MR. SCHMIDT: May we get a copy of the article?

6 MR. FARRELL: You can have mine.

7 MR. SCHMIDT: Thank you. I appreciate that.

8 BY MR. FARRELL:

9 **Q.** Let me ask you one more sentence and see whether
10 you agree with this or not.

11 "The magnitude, severity, and chronic nature of the
12 opioid epidemic in the United States is of serious concern
13 to clinicians, the government, the general public, and
14 others."

15 Do you agree with that statement, sir?

16 **A.** Yes, I do.

17 MR. FARRELL: Judge, if you'll give me a second
18 here to clean up and --

19 THE COURT: Yes, sir.

20 BY MR. FARRELL:

21 **Q.** You mentioned the New England Journal of Medicine.
22 And do you know Dan Longo, Dr. Dan Longo who's the
23 editor by chance?

24 **A.** I don't think that I do, no.

25 **Q.** 2016. I'm going to circulate this to you. But, again,

1 this is a review article much like the 1982. This is, this
2 is from Nora Volkow and Thomas McLellan, a review article
3 reviewed by Dan Longo, the editor.

4 MR. FARRELL: Judge, may I approach?

5 THE COURT: Yes.

6 BY MR. FARRELL:

7 **Q.** I want to kind of go down to the, to the second
8 full paragraph, "However." I'll give you a chance to
9 read it for a second.

10 (Pause)

11 I'll represent for the record that this is March 31st,
12 2016, New England Journal of Medicine, 374 13, titled
13 "Opioid Abuse and Chronic Pain - Misconceptions and
14 Mitigation Strategies" written by Nora D. Volkow, M.D., for
15 the National Institute on Drug Abuse.

16 My question to you is this: Sir, do you agree that
17 opioid analgesics are widely diverted and improperly used?
18 Do you agree with that statement, sir?

19 **A.** I think there is a significant amount of diversion and
20 improper use of opioid analgesics, yes.

21 **Q.** And the widespread use of these drugs has resulted in a
22 national epidemic of opioid overdose, deaths, and
23 addictions. Do you agree with that, sir?

24 **A.** No, I think I would give a more -- I think that's one
25 part of it, but I don't think that's a complete statement as

1 stated.

2 **Q.** Okay. What would you include with it?

3 **A.** So I think there was a contribution by the misuse and
4 abuse of opioid pain medications, the non-medical use of
5 opioid pain medications. But I think there were many other
6 factors that also contributed that the authors are not, not
7 including there, things like the illicit abuse of other
8 illicit drugs and the other factors that we've talked about.

9 I think there were many factors and that that's one.
10 And at least as it's written there, one could take away the
11 impression that it was only one factor.

12 **Q.** And if you look down further, it says, "Second, the
13 major source of diverted opioids is physician
14 prescriptions."

15 Do you agree with that, sir?

16 **A.** Again, yes, but it's incomplete. The major source is
17 that they're prescribed by physicians. And then the major
18 source is people who receive them, then give them to friends
19 or family.

20 **Q.** Right. So the pills -- you can attest today to the
21 Court that the prescription pain pills being prescribed by
22 doctors are being diverted across America?

23 **A.** I can attest today that when the -- when a pill is
24 diverted that the most common scenario is a doctor
25 prescribed it to somebody and then that person subsequently

1 gave it to a friend or family member, sold it to a friend or
2 family member, had it stolen by a friend or family member,
3 et cetera.

4 **Q.** My question to you is whether that is happening, not
5 when it happens, but I'm looking to see whether you
6 acknowledge that it is happening.

7 **A.** Yes, there are certainly instances where a doctor
8 prescribes an opioid to one person and then that opioid
9 subsequently from the patient, or the intended patient gets
10 diverted to someone else after the fact.

11 **Q.** All right, Doctor, you -- last subject matter.

12 You talked earlier, if you remember the *voir dire* that
13 I asked you whether or not you monitored other physicians.
14 You've looked at the monitoring patterns of other physicians
15 in your role, in leadership role in the medical community,
16 have you not?

17 **A.** Yes, I've, I've participated in that monitoring. I've
18 helped in some cases to design that monitoring, yes.

19 **Q.** All right. And, so, you're also aware that some of the
20 medical literature that you've cited in your writings and a
21 lot of the medical literature that you have cited in your
22 expert witness report relies upon the IQVIA prescribing
23 data. Are you familiar with IQVIA?

24 **A.** Yes, I am.

25 **Q.** So you're aware that you can track patterns of doctor

1 prescribing by looking at the IQVIA data?

2 **A.** I'm aware that that's one tool that people have used to
3 try to track that, yes.

4 **Q.** So I'm going to represent to you that I have a good
5 faith basis to ask you a couple questions about --

6 MR. SCHMIDT: We'll object to this. I don't think
7 just showing him -- this is -- if I understand what this
8 document is, this is a document we were given last night
9 that an investigative firm has purportedly gathered from
10 IQVIA regarding Dr. Gilligan's prescribing practices.

11 I don't think it's a proper subject for questioning him
12 on without laying a foundation that he actually recognizes
13 it, which I would be very surprised if he did given the
14 source that it comes from. It's the company that Dr. Keller
15 used to be -- used to work with apparently ran this report.
16 And I think it should be taken down while we're arguing the
17 objection.

18 THE COURT: I'll overrule the objection.

19 BY MR. FARRELL:

20 **Q.** So, Dr. --

21 MR. SCHMIDT: Your Honor, may I just note one
22 other thing for the record?

23 THE COURT: Yes.

24 MR. SCHMIDT: Dr. Keller conceded in her testimony
25 that IQVIA data has various limits. One of those limits is

1 it doesn't pick up hospital data.

2 Dr. Gilligan has spent his whole career working in a
3 hospital, which is a further reason why showing him data
4 that he can't verify is unreliable.

5 THE COURT: Well, that might be a matter for
6 redirect.

7 Go ahead, Mr. Farrell.

8 BY MR. FARRELL:

9 Q. So, Dr. Gilligan, you are a pain medicine doctor;
10 correct?

11 A. That's correct.

12 Q. So what I'll represent to you this is is the IQVIA data
13 for pain medicine doctors in the nation and in West Virginia
14 and then you.

15 UNIDENTIFIED SPEAKER: No.

16 MR. FARRELL: No?

17 UNIDENTIFIED SPEAKER: It's Massachusetts.

18 MR. FARRELL: Oh, it's Massachusetts.

19 BY MR. FARRELL:

20 Q. So when you look at the blue line of pain medicine
21 and you see on the left-hand side dosage units, is this
22 trend in the blue line consistent with what you've
23 testified today about a general rise in prescribing and
24 then more recently a tapering and a decline?

25 A. Yes, it is.

1 **Q.** And when you look at the base line of this from 5,000
2 up to 20,000, that's an increase of three-fold or so. Would
3 you agree?

4 THE COURT: Is that Massachusetts data?

5 MR. FARRELL: The red data is Massachusetts. The
6 blue data is the nation. And the line way down here is the
7 doctor.

8 MR. SCHMIDT: And just so we're clear for the
9 record, Your Honor, this is pain specialists according to
10 however IQVIA, which no witness in this courtroom or
11 probably a lawyer can testify to how they classify people as
12 pain specialists based on the 70 percent of data they have
13 which includes none of hospital data.

14 MR. FARRELL: This is --

15 THE COURT: Well, go ahead, Mr. Farrell. Let's
16 get this done.

17 MR. FARRELL: There is Lacey Keller, the expert
18 who testified that her methodology --

19 MR. SCHMIDT: It's actually not Dr. Keller. She
20 didn't sponsor this.

21 BY MR. FARRELL:

22 **Q.** So would you agree with me that the rise from 5,000
23 up to around 20,000 and the tapering is consistent with
24 the trend that you saw over time?

25 **A.** Yes, I would.

1 Q. And your prescribing patterns are somewhat below the
2 national and the state averages. Would you agree with that?

3 A. Yes, but that's because I work with fellows. So when I
4 see patients, I'm not the one who writes the prescription.
5 I mean, they're trained so the prescriptions on my patients
6 to measure them would show up between ten fellows every
7 year. So they wouldn't show up under my name. They would
8 show up under the different fellows' names.

9 Q. Well, the real point of this was not to show yours, but
10 to show a couple of others.

11 MR. FARRELL: Can you bring up the next one,
12 please?

13 BY MR. FARRELL:

14 Q. I think the next one is Dr. Philip Fisher. Do you
15 know who Dr. Philip Fisher is?

16 A. Not that I remember.

17 Q. All right. Do you see here that the same baseline in
18 blue and red but for West Virginia but the scaling is off.
19 Do you see that?

20 MR. SCHMIDT: Your Honor, we're now examining
21 based on data he can't sponsor about a doctor he said he
22 doesn't know.

23 MR. FARRELL: This is directly --

24 MR. SCHMIDT: And I can't imagine how this is
25 related to the scope of anything I covered, let alone the

1 profound foundation issues.

2 THE COURT: Well, I think I got the point a while
3 ago, Mr. Farrell, and you're just beating it into the
4 ground.

5 MR. FARRELL: Judge, --

6 THE COURT: I'll sustain the objection.

7 MR. FARRELL: Yes, I'm beating it into the ground.
8 I'm trying to demonstrate overwhelmingly that this isn't a
9 sea level change. This is a tsunami.

10 THE COURT: Well, I understand that's where you're
11 going and where you've been going for half an hour and I
12 understand that.

13 MR. FARRELL: So, again, you're giving me the time
14 to move on? I'll do so.

15 THE COURT: Well, I'm giving you a hint that it's
16 time to move on, Mr. Farrell.

17 MR. FARRELL: Yes, Your Honor.

18 BY MR. FARRELL:

19 Q. So you would agree with me that from this pictogram
20 the data from --

21 MR. RUBY: Your Honor, --

22 THE COURT: I'll sustain the objection, Mr.
23 Farrell.

24 MR. FARRELL: How about I go to the next slide?
25 How about we put all of the slides together so that you can

1 see how many doctors are so far in excess of the national
2 and state averages.

3 MR. SCHMIDT: Your Honor, same objection. These
4 are doctors he hasn't reviewed with data that I don't --
5 tell me if I'm wrong. I don't think Dr. Keller sponsored
6 all this data.

7 MR. FARRELL: The point is they just spent three
8 hours talking about the standard of care when we have
9 doctors that went to prison. We have doctors that exceeded
10 the standard of care.

11 MR. SCHMIDT: He's -- I apologize, Mr. Farrell. I
12 interrupted you. I didn't mean to interrupt.

13 Your Honor, standard of care includes wide variations,
14 of course. And there's nothing in his testimony that denied
15 the proposition that doctors who we have no responsibility
16 for, who we don't regulate had the problems Mr. Farrell
17 talked about.

18 We've had a witness that testified about that and you
19 were able to cross-examine her on it. This is completely
20 outside his scope and it's, it's completely untethered from
21 any foundation.

22 THE COURT: Mr. Ruby.

23 MR. RUBY: Your Honor, I simply wanted to amplify,
24 and Mr. Schmidt just said it again, that the foundation
25 point that these are slides with data that no foundation has

1 been laid for. We don't know where these -- we think these
2 came from a company that plaintiffs have paid to put slides
3 together, but no witness has sponsored these and they're
4 being put in front of the witness and he's being asked to
5 testify about them as if they're evidence.

6 THE COURT: I'm going to sustain the objection.
7 You've beaten the same point. If I understand your point,
8 this was made a long time ago and I think you should move
9 on.

10 MR. FARRELL: One last question.

11 BY MR. FARRELL:

12 **Q.** Doctor, you would agree with me that the standard
13 of care does not immunize a doctor from blatantly
14 breaching his obligation to do no harm?

15 **A.** I would agree with you that doctors have an obligation
16 to do no harm. And I don't think that the standard of care
17 would make an exception -- would justify an exception to
18 that.

19 MR. FARRELL: No further questions.

20 THE COURT: Is there anymore?

21 MR. ACKERMAN: I have a couple, Your Honor.

22 THE COURT: Go ahead, Mr. Ackerman.

23 Let's take 10 minutes.

24 MR. ACKERMAN: Okay.

25 (Recess taken at 2:50 p.m.)

1 THE COURT: All right. Mr. Ackerman.

2 CROSS EXAMINATION

3 BY MR. ACKERMAN:

4 Q. Good afternoon, Dr. Gilligan. 3:00 on the Friday
5 before July 4th weekend is not exactly prime time, so I'm
6 going to do my best to keep this as short as possible. I
7 want to ask you just about a couple of questions that Mr.
8 Schmidt went through this morning.

9 The first one is MCWV-1522.

10 MR. ACKERMAN: Gina, if you can pull that up.

11 BY MR. ACKERMAN:

12 Q. And, Dr. Gilligan, I don't know if you have that in
13 front of you. Dr. Gilligan, this is -- Document 1522 is the
14 joint statement from 21 health organizations and the Drug
15 Enforcement Administration, correct?

16 A. That is correct.

17 Q. And this is a -- you said it was a notice to the
18 medical community that went out around 2001, correct.

19 A. That's correct.

20 Q. And if you would look, sir, at the second to last
21 paragraph, the one that starts drug abuse is a serious
22 problem. Do you see that?

23 A. I do.

24 Q. And that paragraph reads drug abuse is a serious
25 problem. Those who legally manufacture, distribute,

1 prescribe and dispense controlled substances must be mindful
2 of and have respect for their inherent abuse potential.

3 Correct?

4 **A.** I see that, yes.

5 **Q.** And that's contained within this notice to the medical
6 community, correct?

7 **A.** That's correct.

8 **Q.** Let's put that document aside. One more document, Dr.
9 Gilligan, and that is the first document we went through
10 today and I guess probably the biggest. It's MCWV-1170.

11 Dr. Gilligan, this is the -- this is the publication by
12 -- I think you said it was from the Institute of Medicine;
13 is that right?

14 **A.** That's right.

15 **Q.** And would you just remind, at least me, what is the
16 Institute of Medicine?

17 **A.** So, it's a group of typically very well respected
18 physicians who are tasked by the government with writing
19 reports at different times on different health topics that
20 are important to Americans. This report had different pain
21 medicine specialists and then some patient representatives,
22 et cetera.

23 **Q.** Okay. If you would turn, sir, to the page that says --
24 Page 163 in the little numbers in the lower left-hand
25 corner, please, and there's a heading that says

1 Effectiveness of Opioids As Pain Relievers. Let me know
2 when you're there.

3 **A.** I'm there.

4 **Q.** Okay. And do you see where it says Effectiveness of
5 Opioids as Pain Relievers? Do you see that section?

6 **A.** I do.

7 **Q.** And there's a sentence that says the effectiveness of
8 opioids as pain relievers, especially over the long-term, is
9 somewhat unclear, correct?

10 **A.** I -- I see that.

11 **Q.** And then there are number of bullet points talking
12 about different studies of the effectiveness of opioids;
13 would you agree with that?

14 **A.** Yes, I would.

15 **Q.** And if you look at that last bullet point, it discusses
16 a metaanalysis of studies involving back pain. Do you see
17 that reference?

18 **A.** I do.

19 **Q.** And that sentence says a metaanalysis of studies
20 involving back pain did not show that opioids reduced pain.
21 Did I read that correctly?

22 **A.** Yes, you did.

23 **Q.** And then the next sentence says they also found that
24 Substance Use Disorders are common in patients taking
25 opioids for back pain with as many as one fourth of these

1 patients showing abhorrent medication taking behavior. Did
2 I read that correctly?

3 **A.** Yes, you did.

4 **Q.** And that's one finding from the Institute of Medicine,
5 correct?

6 **A.** That is one point that they make, yes.

7 **Q.** And do you have an understanding of what abhorrent
8 medication taking behavior means?

9 **A.** Yes, I do.

10 **Q.** And what is that?

11 **A.** That's not taking your medications as prescribed.
12 That's taking them -- could be more -- more frequently than
13 prescribed, not following other instructions. For example,
14 don't drink alcohol and take this medication and then taking
15 them with alcohol would be an abhorrent use. So, taking
16 them essentially and not following the instructions that
17 were given in terms of how to take them and it would also
18 include misusing or abusing them.

19 **Q.** Thank you. If you would then, sir, turn to the page
20 that is number 165. Actually, I'm sorry. Further down on
21 Page 164. Let me know when you're there. There's a heading
22 that says Need for Education.

23 **A.** I'm there.

24 **Q.** Okay. And the last sentence of that paragraph reads,
25 however, data from a 2009 survey conducted by SAMHSA, and

1 you understand what SAMHSA is, right?

2 **A.** Yes, I do.

3 **Q.** Indicate that some 5 million Americans used pain
4 relievers non-medically in the month prior to the survey and
5 that these medications generally were the result of a
6 medical prescription. Do you see that sentence?

7 **A.** I do.

8 **Q.** And that's another finding of the Institute of
9 Medicine, right?

10 **A.** That's another point that they include in their report,
11 yes.

12 **Q.** Thank you. Now, if we go to the next page, Page 165 --

13 MR. ACKERMAN: And we're getting close to the end,
14 Your Honor.

15 BY MR. ACKERMAN:

16 **Q.** There's a section that says Abuse of Opioids. Do you
17 see that?

18 **A.** Yes, I do.

19 **Q.** And there's a reference here that says the diversion of
20 opioid analgesics has become a national public health
21 problem. Do you see that?

22 **A.** Yes, I do.

23 **Q.** And that's yet another topic that the Institute of
24 Medicine included in this report, right?

25 **A.** Yes, it is.

1 **Q.** And if you go down to the bottom of the page, sir,
2 there is a sentence -- there is a paragraph that reads
3 opioid medications present some risk. Do you see that
4 paragraph?

5 **A.** Yes, I do.

6 **Q.** And that paragraph reads opioid medications present
7 some risk of abuse by patients, as well, and then it talks
8 about a review of -- of studies. Do you see -- do you see
9 where I am?

10 **A.** I think so. Structured review of 67 studies.

11 **Q.** Yes. And there's a reference at the back that says 12
12 percent developed abhorrent drug-related behavior. Do you
13 see that reference?

14 **A.** I do.

15 **Q.** And that's 12 percent of chronic non-cancer pain
16 patients regularly taking opioids; is that right?

17 **A.** That's right. The sentence has more to it. It also
18 includes that 3 percent take a -- develop opioid abuse or
19 addiction, as opposed to the 12 percent.

20 **Q.** Yes, yes. And you're right. The finding is that 3
21 percent developed opioid abuse or addiction, correct?

22 **A.** Correct.

23 **Q.** And then 12 percent developed abhorrent drug-related
24 behavior?

25 **A.** Correct.

1 **Q.** And what -- do you have an understanding of what
2 abhorrent drug-related behavior is?

3 MR. SCHMIDT: I think that was asked and answered
4 two minutes ago, Your Honor.

5 MR. ACKERMAN: So, I think it's a little bit --

6 BY MR. ACKERMAN:

7 **Q.** Is that the same as the abhorrent medication taking
8 behavior that we just discussed?

9 **A.** Yes. It's the same.

10 **Q.** And then the very next sentence talks about another
11 analysis and it says a recent analysis revealed that half of
12 patients who received a prescription for opioids in 2009 had
13 filled another opioid prescription within the previous
14 30 days. Do you see that?

15 **A.** I do.

16 **Q.** And that's yet another finding that the Institute of
17 Medicine made in this document, correct?

18 **A.** Correct.

19 **Q.** Okay. Last point, which is on the next page, Page 166,
20 sir, there is a heading that says Opioid Use and Costs of
21 Care. Do you see that?

22 **A.** I do.

23 **Q.** Okay. And that paragraph begins and says opioid use
24 may increase the costs of care. Did I read that correctly?

25 **A.** Yes, you did.

1 **Q.** And that's a finding from this Institute of Medicine,
2 right?

3 **A.** That's a point in their report, yes.

4 **Q.** Okay. And then, sir, would you read into the record
5 the last sentence of that paragraph, which is on the next
6 page, Page 167.

7 MR. RUBY: Your Honor -- Your Honor, objection.
8 Cost of care is well beyond the scope of the direct exam.

9 THE COURT: Sustained.

10 MR. ACKERMAN: Your Honor --

11 THE COURT: Let's get this done, Mr. Ackerman.

12 MR. ACKERMAN: This is the last question, is
13 reading this one sentence into the record, but this is a
14 document that defendants introduced and they selectively
15 introduced parts of it and under Rule 106 --

16 THE COURT: Okay. Let him read it and let's get
17 this done.

18 MR. ACKERMAN: Thank you.

19 BY MR. ACKERMAN:

20 **Q.** Dr. Gilligan, would you please read the last sentence
21 of this paragraph into the record?

22 **A.** A conservative estimate of the cost to society of
23 prescription opioid abuse in the United States is
24 \$9.5 billion dollars in 2005 -- or excuse me -- \$9.5 billion
25 in 2005 dollars.

1 MR. ACKERMAN: Thank you.

2 Nothing further, Your Honor.

3 MR. SCHMIDT: May I proceed, Your Honor?

4 THE COURT: Yes.

5 **REDIRECT EXAMINATION**

6 **BY MR. SCHMIDT:**

7 **Q.** Let's pick back up with MCWV-1170 just to complete a
8 few points regarding this Institute of Medicine study and
9 let's start on Page 163, right where you were just asked
10 questions about, Dr. Gilligan, under the heading
11 Effectiveness of Opioids as Pain Relievers, and it says --
12 language you were just read on cross examination, the
13 effectiveness of opioids as pain relievers, especially over
14 the long-term, is somewhat unclear. Do you remember being
15 asked about that language?

16 **A.** I do.

17 **Q.** Is that consistent with what you told us on direct
18 about study data on chronic -- on the use of opioids with
19 chronic non-cancer pain?

20 **A.** Yes. It's exactly consistent with that.

21 **Q.** Do you have an understanding as to how much of opioid
22 use has occurred is for acute pain versus chronic non-opioid
23 pain?

24 **A.** Excuse me. How much of opioid use is for acute pain
25 versus chronic non-cancer pain?

1 Q. Yes, Doctor.

2 A. I'm not sure that I know an exact numerical number on
3 that. I -- I believe that chronic non-cancer pain would be
4 -- would be higher numbers, although I'm actually not sure
5 numerically on that point.

6 Q. Okay. Fair enough. I want to just show you a couple
7 of the findings here that we didn't get a chance to cover.
8 The first bullet says in a metaanalysis of randomized
9 controlled trials involving non-cancer pain, researchers
10 concluded that the relative effectiveness and risk or
11 benefit of opioids compared with other non-opioid treatments
12 are still to be determined. Do you see that?

13 A. I do.

14 Q. Is that consistent with what you told us on direct?

15 A. Yes, that is.

16 Q. If you go to the next, Page 164, and let's look above
17 that heading, Need For Education, the first paragraph above
18 that heading. They reference those research findings above
19 and they say the research findings noted above need to be
20 set against the testimony of people with pain, many of whom
21 derive substantial relief from opioid drugs. Do you see
22 that?

23 A. I do.

24 Q. Is that consistent with what you told us on direct
25 exam, that individual patient experiences have to be weighed

1 against this study data that is less conclusive?

2 **A.** Yes, it is.

3 **Q.** Let's go to Page 3. I'm sorry. Let's go to Page 165.
4 I apologize.

5 You were asked about language in this section and I
6 want to show you the second paragraph under Abuse of
7 Opioids. And do you see there's a sentence five lines down
8 near the end of the line that says more than half?

9 **A.** I do.

10 **Q.** More than half, 55 percent in this study of non-medical
11 users of prescription pain relievers obtained the drugs they
12 used most recently from a friend or relative for free; that
13 is, they did not buy or steal them. Is that data that
14 you've seen repeatedly throughout your work that is a
15 concept we've heard of in court called diversion from the
16 medicine cabinet?

17 **A.** Yes, that is.

18 **Q.** Let's go to Page 166. You were asked some questions
19 about this section on abuse of opioids and you'll see
20 there's language above these bullet points that say --

21 MR. SCHMIDT: And I'm actually going to need to
22 capture the sentence above and then the bullet points,
23 please.

24 BY MR. SCHMIDT:

25 **Q.** Current voluntary strategies to reduce opioid abuse

1 include, and then do you see that there is a reference to
2 various programs?

3 **A.** I do.

4 **Q.** Do you see that the first one focuses on doctors?

5 **A.** Yes, I do.

6 **Q.** Do you see that the second one focuses on doctors?

7 **A.** I do.

8 **Q.** Do you see that the third one focuses on patients and
9 how doctors care for patients?

10 **A.** I do.

11 **Q.** Next one talks about state Prescription Drug Monitoring
12 Programs. Do you see that?

13 **A.** Yes, I do.

14 **Q.** Next one talks about new drug formulations by
15 manufacturers. Do you see that?

16 **A.** Correct.

17 **Q.** And do you see the next one talks about removing unused
18 drugs from home medicine cabinets and take-back events? Do
19 you see that?

20 **A.** Yes, I do.

21 **Q.** Do any of those specifically speak to conduct by
22 distributors as you understand them?

23 **A.** No, they do not.

24 **Q.** All right. And last question on this document. Do you
25 recall being asked about the costs of opioid use?

1 **A.** Yes, I do.

2 **Q.** Let's go to Page 164, please. And right above the
3 heading Need For Education there's some language that's
4 italicized for emphasis. It says, regardless, the majority
5 of people with pain use their prescription drugs properly,
6 are not a source of misuse, and should not be stigmatized or
7 denied access because of the mis-deeds or carelessness of
8 others. Do you have an understanding if that view of the
9 Institute of Medicine is widely held within medicine?

10 **A.** Yes, I do.

11 **Q.** Let's go to another document, MCWV-1522. This is the
12 2001 joint statement from the DEA, the AMA and 20 other
13 healthcare organizations. You were shown a sentence in the
14 second paragraph from the bottom.

15 BY MR. SCHMIDT: If you can cull up that whole
16 paragraph.

17 BY MR. SCHMIDT:

18 **Q.** Do you remember being asked about the second sentence
19 to those who legally manufacture, distribute, prescribe and
20 dispense controlled substances?

21 **A.** Yes, I do.

22 **Q.** Let's look at the very next sentence. Focusing only on
23 the abuse potential of a drug, however, could erroneously
24 lead to the conclusion that these medications should be
25 avoided when medically indicated generating a sense of fear

1 rather than respect for their legitimate properties. Do you
2 see that?

3 **A.** Yes, I do.

4 **Q.** And, again, did you understand that to be guidance that
5 the medical profession and the healthcare system was
6 receiving at this time from the DEA, from groups like the
7 AMA?

8 **A.** Yes, I do.

9 **Q.** Let's go to your presentation, P-41958, and see if we
10 can cull it up on the screen. And I would like to go to
11 Page 20. Let's start on Page 30, please.

12 You were shown this map. And I just want to orient you
13 to the language used where it talks about sales and
14 kilograms. Do you see that?

15 **A.** I do.

16 **Q.** And then, if we go back to Page 29, please, again,
17 Discussion of Sales. Do you see that?

18 **A.** I do.

19 **Q.** And there was a little colloquy between you and Mr.
20 Farrell regarding sales for prescriptions. Why is it in
21 these documents that you reference sales and sales per
22 kilogram?

23 **A.** Because that's the unit that CDC uses to report it, but
24 I used it to make a teaching point to physicians about
25 over-prescribing.

1 **Q.** And that's what I want to see if I can understand, Dr.
2 Gilligan. What is the relationship, if any, between sales
3 and prescribing?

4 **A.** So, with a controlled substance that's a prescription,
5 it's a linked relationship. There is not a sale of a gram
6 or a kilogram without a prescription. So, sales only go up
7 as prescriptions go up. So, sales is a surrogate for
8 prescribing. So, that's why, since it's reported in this
9 unit, I had to use it in this unit, but the teaching point
10 for the doctors was entirely on over-prescribing because
11 sales only occur when a doctor or another clinician writes a
12 prescription.

13 **Q.** And prescriptions cause sales?

14 **A.** Yes. There is no sale without a prescription.

15 **Q.** One more question on this document. You were asked
16 about some of the data, including the reference here to
17 abuse. Do you see that?

18 **A.** Yes.

19 **Q.** And I want to just jump ahead to Page 32 of this
20 document. And do you see you've provided further data on
21 people who abuse prescription pain-killers getting their
22 drugs from a variety of sources? Do you see that?

23 **A.** I do.

24 **Q.** And just -- if we look at three of them, obtained free
25 from friend or relative, 55 percent, in the bottom left, and

1 then, upper right, the third one, took from friend or
2 relative without asking, 4.8. And then, below that, bought
3 from friend or relative, 11.4. Do you see that?

4 **A.** I do.

5 **Q.** And what's the data source for this data you're
6 reporting here?

7 **A.** That's from the CDC.

8 **Q.** And so, according to this data, do we get about
9 70 percent of people who are abusing prescription
10 pain-killers get them from, in one way or another, a friend
11 or relative?

12 **A.** That's correct.

13 **Q.** Let's look at the Volkow article you were shown,
14 P-43172, and just a couple simple questions about this
15 article. I think you were shown language down at the bottom
16 of the first page here in the last full paragraph where it
17 says second. Do you see that?

18 **A.** I do.

19 **Q.** It says, second, the major source of diverted opioids
20 is physician prescriptions. Do you see that?

21 **A.** I do.

22 **Q.** And, first of all, are you aware that this is an
23 article from -- and we can look at the bottom, if you want.
24 You can kind of see it down here at the bottom. 2016.

25 **A.** Yes, I'm aware.

1 **Q.** Did you understand, if we pull that down, that
2 statement to be accurate at that time, that the major source
3 of diverted opioids is physician prescriptions?

4 **A.** Yes, I do understand that to be accurate.

5 **Q.** They then say, for these reasons, physicians and
6 medical associations have begun questioning prescribing
7 practices for opioids, particularly as they relate to the
8 management of chronic pain. Do you see that?

9 **A.** I do.

10 **Q.** How did that relate to what you told us earlier in
11 terms of changing standards of care from the medical
12 profession about how they prescribe or don't prescribe
13 prescription opioids?

14 **A.** So, that's that later phase. This is from 2016, where
15 physicians had more awareness of the potential harms, more
16 awareness of some limitations on the data on efficacy and,
17 therefore, started to prescribe more conservatively.

18 **Q.** Two other small points in this article. Could we go to
19 Page 5, please? You -- when you were talking about this
20 article, I thought I heard you give an answer about
21 something being partly true and I thought I heard you refer
22 to other factors being important. Am I recalling that
23 correctly? I'm probably butchering that horribly.

24 **A.** No. I think that is a correct statement.

25 **Q.** Let me show you some specific other factors. If we

1 look at the left-hand column, first full paragraph in the
2 middle, it says however. Do you see that? However, we do
3 know that the risk of opioid addiction varies substantially
4 among persons. Do you see that?

5 **A.** I do.

6 **Q.** Is that accurate in your view?

7 **A.** Yes, and that relates to some of the things we've
8 talked about today.

9 **Q.** And it then says the genetic vulnerability accounts for
10 at least 35 to 40 percent of the risk associated with
11 addiction. Do you see that?

12 **A.** I do.

13 **Q.** And then they talk about adolescents being at an
14 increased risk. Do you see that?

15 **A.** I do.

16 **Q.** And are these some of the factors that you were talking
17 about that are important to consider, things like genetic
18 vulnerability, accounting for at least 35 to 40 percent of
19 the risk associated with addiction?

20 **A.** Yes. That's exactly an example of the sort of factors
21 for who is going to be high risk, who's going to be medium
22 risk, who's going to be low risk, why it's relevant to ask a
23 patient not just do you have a history of substance abuse
24 yourself, but do you have a family history of substance
25 abuse. It's not a judgment on someone, but it's identifying

1 a risk factor in order to try to keep them safe.

2 **Q.** Let's go to Page 7, please, under Conclusions. The
3 very bottom, it says, although there are no simple
4 solutions, we recommend three practice and policy changes
5 that can reduce abuse-related risks and improve the
6 treatment of chronic pain. Do you see that?

7 **A.** I do.

8 **Q.** And then, if we go to the next page, please, we can see
9 it hopefully culled out and it looks like the first is
10 increased use of science supported prescribing and
11 management practice. And then the next one is increased
12 medical school training on pain and addiction. Do you see
13 that?

14 **A.** I do.

15 **Q.** And the third one is increased research on pain,
16 including potentially research on prescription opioids. Do
17 you see that?

18 **A.** I do.

19 **Q.** Are any of those focused on distributors, as you
20 understand them?

21 **A.** No.

22 **Q.** Let's look at the McCabe article, please, P-43594.
23 This is the one from 2021, the longitudinal study. And
24 let's just look at some language we didn't have a chance to
25 see.

1 If we look in the bottom right corner of the first page
2 in this article it says most adolescents who are prescribed
3 opioids use them appropriately without an increased risk for
4 substance misuse. Do you see that?

5 **A.** I do.

6 **Q.** Is that consistent with the broader data, as you
7 understand it?

8 **A.** Yes. That is consistent with the broader data.

9 **Q.** And then you were asked about a commentary on this
10 article from Compton. Do you remember that?

11 **A.** I do.

12 **Q.** Let's look at that very quickly, P-41929, and it looks
13 like they have a summary of their commentary here. Do you
14 see that?

15 **A.** I do.

16 **Q.** They talk about the McCabe study. Do you see that
17 reference?

18 **A.** I do.

19 **Q.** And then they talk about the key findings. Do you see
20 that?

21 **A.** I do.

22 **Q.** And the key findings that they reference are an overall
23 association. Do you see that?

24 **A.** I do.

25 **Q.** And we talked about this earlier, but I just wanted to

1 be clear. What is the difference between association and
2 causation?

3 **A.** So, an association is two things that have happened
4 together that go together, but they may not be one causing
5 the other, but there might be other causes that are just
6 causing the two things to occur at the same time, for
7 example.

8 **Q.** And do you remember --

9 MR. SCHMIDT: If we can pull that page down, but
10 keep the document.

11 BY MR. SCHMIDT:

12 **Q.** Do you remember being asked about an earlier Compton
13 article?

14 **A.** Yes, I do.

15 **Q.** Let's take a look at that earlier Compton article
16 really quickly, DEF-WV-2646. Do you recognize this as a
17 publication by Wilson Compton, New England Journal of
18 Medicine?

19 **A.** Yes, I do.

20 **Q.** And the title is Relationship Between Non-Medical
21 Prescription Opioid Use and Heroin Use. Do you see that?

22 **A.** I do.

23 **Q.** So, is this another example of analyzing people who are
24 misusing prescription opioids and seeing if that happens
25 before heroin use?

1 **A.** Yes, it is.

2 **Q.** Let's look at Page 7, please, of this article. Under
3 the conclusions, let's look at the second paragraph, please.

4 The transition from non-medical use of prescription
5 opioids to heroin use appears to be part of the progression
6 of addiction in a sub-group of non-medical users of
7 prescription opioids primarily among persons with frequent
8 non-medical use and those with prescription opioid abuse or
9 dependence.

10 Let me stop there. What do you understand that to be
11 saying?

12 **A.** So, they're saying when people go from non-medical use
13 of opioid pain-killers to using heroin, that that's part of
14 a progression of an addiction among this group of
15 non-medical users who frequently engage in the non-medical
16 use.

17 **Q.** And when -- when you have, from your experience and
18 your understanding of the science, when you have a
19 progression of addiction from one substance to another, can
20 you say that that same path wouldn't be followed by other
21 substances if you took out one substance in the pack?

22 **A.** No, you can't.

23 **Q.** The next sentence says, although some authors suggest
24 that there is an association between policy driven
25 reductions in the availability --

1 MR. FARRELL: Judge, I'm going to object to this
2 because I don't want to have to redirect. This is outside
3 the scope and talks about PDMP and state laws and the impact
4 on opioid prescribing.

5 THE COURT: Well, that's right, isn't it, Mr.
6 Schmidt?

7 MR. SCHMIDT: I think that is true, but this is an
8 article he was asked about, and it goes to the subject that
9 he was asked about in terms of links between prescription
10 opioid misuse and heroin.

11 THE COURT: Well, overruled. Go ahead.

12 BY MR. SCHMIDT:

13 **Q.** It says, although some authors suggest that there is an
14 association between policy driven reductions and the
15 availability of prescription opioids and increases in the
16 rates of heroin use, the timing of these shifts, many of
17 which began before policies were robustly implemented makes
18 a causal link unlikely. Do you see that?

19 **A.** Yes, I do.

20 **Q.** What do you understand that to mean?

21 **A.** That what they're saying is that the shift from people
22 who were misusing prescription opioids, abusing them,
23 shifting to heroin was not driven by policies of decreased
24 opioid prescribing, that the timing doesn't add up and that
25 you can't say there was causation there.

1 **Q.** Let's look at what they say immediately below that and
2 I'll go on to just one or two more topics.

3 They say, alternatively, heroin market forces,
4 including increased accessibility, reduced price, and high
5 purity of heroin appear to be major drivers of the recent
6 increases in rates of heroin use. Do you see that?

7 **A.** Yes, I do.

8 **Q.** Are you familiar from the scientific literature with
9 studies, some discussed in this article, talking about the
10 influence of heroin market forces, including increased
11 accessibility, reduced price in high purity, and serving as
12 major drivers of increases in heroin use?

13 **A.** Yes, I am.

14 **Q.** I'm going to take a gamble, if I could, and see if I
15 can go back to the white board and hope that it's there
16 still. That didn't work. Let me try one more time.

17 MR. SCHMIDT: If that doesn't work, I'll move on,
18 Your Honor.

19 It's not there. Okay.

20 BY MR. SCHMIDT:

21 **Q.** Do you remember the white board we drew with the
22 numbers? I think it was 79.5 percent who -- of people who
23 had used heroin who had previously used prescription
24 opioids?

25 **A.** Yes, and it was 79.5 percent.

1 **Q.** I may get the number wrong, but I think it was 98.9
2 percent of the same number of people who had used heroin had
3 used other illegal drugs?

4 **A.** Yes, and it was 98.9 percent.

5 **Q.** Okay. With that idea in mind, you talked in the
6 context of talking about the Seattle talk given in Las Vegas
7 that people transitioned. Do you remember being asked
8 questions about that?

9 **A.** Yes, I do.

10 **Q.** In the same way, did people transition from using those
11 illegal drugs to using illegal heroin and fentanyl?

12 Oh, and there it is. So, let me ask my question again.

13 You talked about the number of people who transitioned
14 from misuse of prescription opioids to heroin. Do you
15 remember that?

16 **A.** I do.

17 **Q.** And in the same way that a number of people transition
18 from using these illegal drugs, cocaine, crack, marijuana,
19 others to heroin?

20 **A.** Yes, they did.

21 **Q.** And are there other factors beyond those discussed in
22 some of these studies, like the mental health history, the
23 family history, discussed in the article that also
24 contributed to this transition?

25 **A.** Yes, because those are the risk factors that predispose

1 to substance abuse in general, including these different
2 types.

3 **Q.** Does the risk of someone transitioning vary by
4 medication?

5 **A.** I think it does in the sense that there are some people
6 who are going to be at higher risk to transition to heroin
7 than others.

8 **Q.** And do you know how much different, if any, heroin
9 rates would be if this type of illegal drug abuse were
10 exactly the same and there was less misuse of prescription
11 opioids? Can we tell that?

12 **A.** No. I don't think you can tell that.

13 **Q.** I want to just touch on two more small topics.

14 From your experience as a doctor, does every
15 prescription medicine carry some form of risk?

16 **A.** Yes.

17 **Q.** And as you prescribe a medication with known risks at a
18 higher level, as doctors do across society, do you expect to
19 see more of the known risks of the medicine, whatever they
20 might be?

21 **A.** Yes. If you prescribe a higher -- or doctors in
22 general prescribe a higher volume of a given medication, you
23 will see more of whatever the adverse effect associated with
24 that medication is in general, yes.

25 **Q.** So, why do doctors prescribe medications?

1 **A.** Because they're -- at least with that individual
2 patient, at that moment, they made a judgment. They might
3 -- hopefully, it would be right, almost always, but in some
4 cases it might even be wrong. But their judgment at that
5 moment was that the benefits for that patient outweighed the
6 risks and, therefore, justified prescribing that medication
7 at that dose at that time.

8 **Q.** When you studied and looked for changes in the standard
9 of care under which opioid prescribing went up, as I
10 understood your testimony earlier, doctors became more aware
11 over time of the risks of addiction and things -- and
12 associated problems; is that fair?

13 **A.** That's correct. Over time, doctors gained an
14 increasing awareness of the risks of opioid pain
15 medications.

16 **Q.** Were doctors always aware, though, that there was some
17 risk of addiction with prescription opioids throughout that
18 time period you were looking at?

19 **A.** Yes. Throughout that time period and, actually, for
20 many -- for decades. Prior to that, doctors have known that
21 those medications have risks, including abuse, addiction, et
22 cetera.

23 **Q.** Did they understand risks of death even?

24 **A.** Yes.

25 **Q.** And so, why did they prescribe more from your

1 understanding?

2 **A.** Again, because of this balance of risk versus benefit,
3 that their feeling was that, in those instances, the
4 benefits outweighed the risks.

5 **Q.** Do you know of distributors playing any role in that
6 process?

7 **A.** Distributors played no role in that process.

8 **Q.** Last question. You were asked about a -- last set of
9 questions. I'm sorry.

10 You were asked about a book called Dreamland. Do you
11 remember being asked about that, Dreamland, that book that
12 you said you read?

13 **A.** Yes, I do.

14 **Q.** Do you recall in that book whether there are chapters
15 and chapters talking about the role of Purdue?

16 **A.** There were, yes.

17 **Q.** Do you recall whether there are chapters in that book
18 talking about drug cartels and new steps they took to get
19 heroin to people, aggressive new delivery techniques making
20 it like pizza?

21 **A.** Yes. I remember that.

22 **Q.** We looked through that book. We couldn't find any
23 mention of distributors. Do you recall any discussion of
24 distributors in there?

25 **A.** I don't remember any discussion of distributors in that

1 book.

2 **Q.** We looked through that book. We couldn't find any
3 mention of AmerisourceBergen, McKesson, Cardinal. Do you
4 recall any reference to them in that book?

5 **A.** I don't recall any reference to the distributors in
6 that book.

7 MR. SCHMIDT: Thank you, Dr. Gilligan.

8 THE COURT: Do you have anything else?

9 MR. FARRELL: No, Your Honor.

10 THE COURT: May I excuse Dr. Gilligan?

11 Thank you, sir, very much. You're free to go.

12 THE WITNESS: Thank you, Your Honor.

13 THE COURT: We appreciate it.

14 THE WITNESS: Thank you.

15 THE COURT: Are we done until next Wednesday?

16 Everybody say yes.

17 SIMULTANEOUS SPEAKERS: Yes, Your Honor.

18 THE COURT: All right. I hope everybody enjoys
19 the holiday and I'll see everybody Wednesday morning at
20 9:00.

21 (Trial recessed at 4:10 p.m.)

22

23

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1 CERTIFICATION:

2 I, Ayme A. Cochran, Official Court
3 Reporter, and I, Lisa A. Cook, Official Court Reporter,
4 certify that the foregoing is a correct transcript from
5 the record of proceedings in the matter of The City of
6 Huntington, et al., Plaintiffs vs. AmerisourceBergen
7 Drug Corporation, et al., Defendants, Civil Action No.
8 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as
9 reported on July 2, 2021.

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11 S\Ayme A. Cochran

12 Reporter

13 s\Lisa A. Cook

14 Reporter

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16 July 2, 202117 Date
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